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# Healthcare delivery models for heart failure

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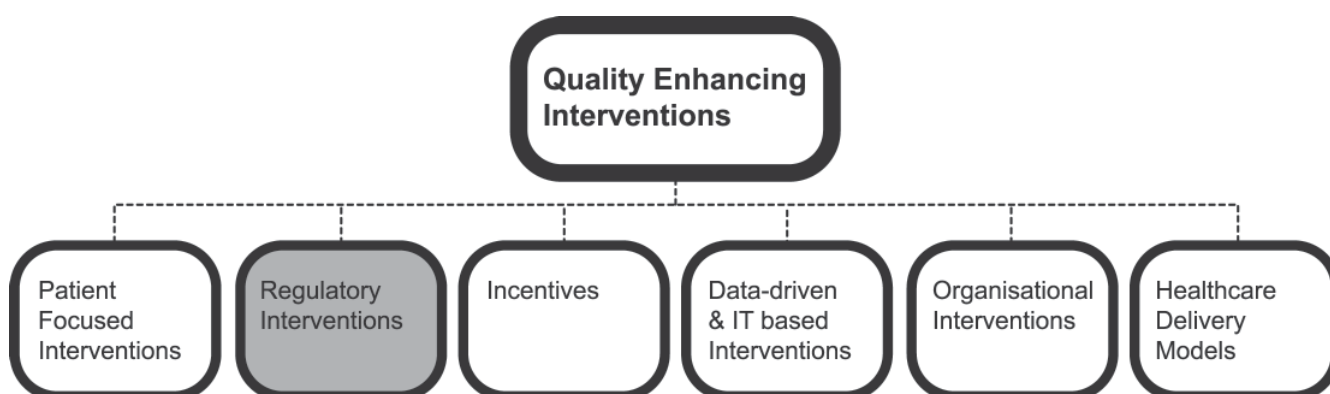
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## QQUIP and the Quality Enhancing Interventions project

QQUIP (Quest for Quality and Improved Performance) is a five-year research initiative of The Health Foundation. QQUIP provides independent reports on a wide range of data about the quality of healthcare in the UK. It draws on the international evidence base to produce information on where healthcare resources are currently being spent, whether they provide value for money and how interventions in the UK and around the world have been used to improve healthcare quality.

The Quality Enhancing Interventions component of the QQUIP initiative provides a series of structured evidence-based reviews of the effectiveness of a wide range of interventions designed to improve the quality of healthcare. The six main categories of Quality Enhancing Interventions for which evidence will be reviewed are shown below.



All the information generated through QQUIP will be available at [www.health.org.uk/qquiip](http://www.health.org.uk/qquiip)

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## Executive summary

**Heart failure** is the term used to describe the symptoms and signs that occur if the heart becomes less efficient at pumping blood around the body, either at rest or during activity. Heart failure may be the result of damage to the heart muscle. The damage is most typically caused by a heart attack. Heart failure can also be caused by conditions that put an extra workload on the heart. The heart may have coped with this extra workload for years before heart failure occurs. These conditions include high blood pressure (hypertension), anaemia, diseased heart valves, thyroid gland disease or an excessively slow or fast heart rate (British Heart Foundation, 2006).

Heart failure represents a serious health system challenge. It accounts for 1 million inpatient days (2 per cent of all National Health Service [NHS] inpatient bed days) and 5 per cent of all emergency medical admissions to hospital (The National Collaborating Centre for Chronic Conditions, 2003). Hospital admissions for heart failure are expected to rise by 50 per cent over the next 25 years largely because of the ageing of the population and the accompanying increase in the underlying causes of heart failure such as coronary heart disease. Patients with heart failure tend to have frequent and prolonged hospital admissions. As a result, caring for these patients is costly, with estimates of the annual cost of heart failure to the NHS ranging from £400m (Cowie, 2002) to £716m (The National Collaborating Centre for Chronic Conditions, 2003), or around 1.8 per cent of the total NHS budget; much of this cost is attributed to the cost of hospitalisation (The National Collaborating Centre for Chronic Conditions, 2003).

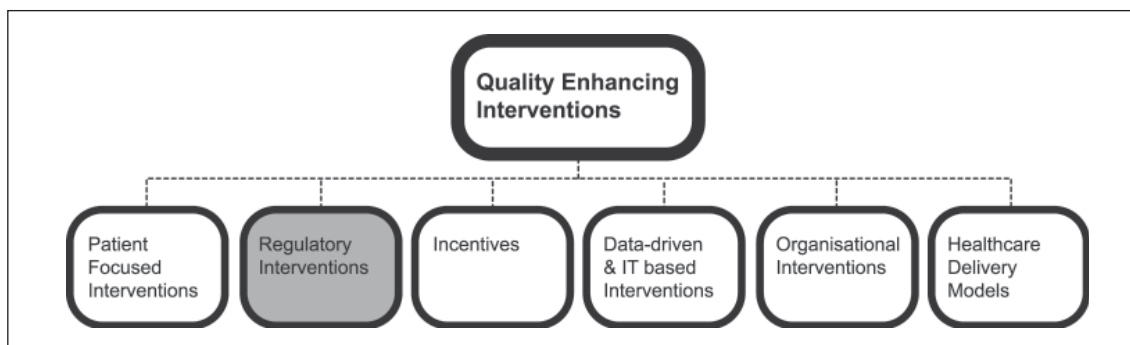
The underlying causes of, and effective treatments for, heart failure are well understood. This information has underpinned the development of multiple evidence-based guidelines for the treatment of this serious condition (Hunt, 2005; Arnold et al, 2006; Swedberg et al, 2005). Nevertheless, heart failure continues to cause significant morbidity and mortality, quite apart from substantial direct healthcare spending. The imbalance between knowledge of heart failure treatment and effective delivery of guideline-concordant care suggests what Woolf and Johnson characterise as a lack of 'fidelity' in the heart failure care delivered; fidelity in this context refers to 'the extent to which the system provides patients the precise interventions they need, delivered properly, precisely when they need them' (Woolf and Johnson, 2005, p 545).

The emphasis of the evidence summarised in this report, therefore, is not effective clinical treatments per se but rather evidence regarding health system delivery modalities related to the care of heart failure patients.

## Project overview

What works to improve quality in healthcare is a perennial question. Health services research, clinical medicine and social science literature all contain a huge number of articles that discuss interventions designed to improve quality. The interventions vary widely in terms of design, underlying assumptions and the context in which they have been implemented. However, although the number of publications that discuss quality improvement is unwieldy and ever increasing, the empirical evidence about the effects such interventions have on healthcare processes and outcomes is sparse and difficult to access. The Quality Enhancing Interventions (QEI) project seeks to address these difficulties and is gathering together available evidence on a range of interventions designed to improve quality of care (see Figure 1).

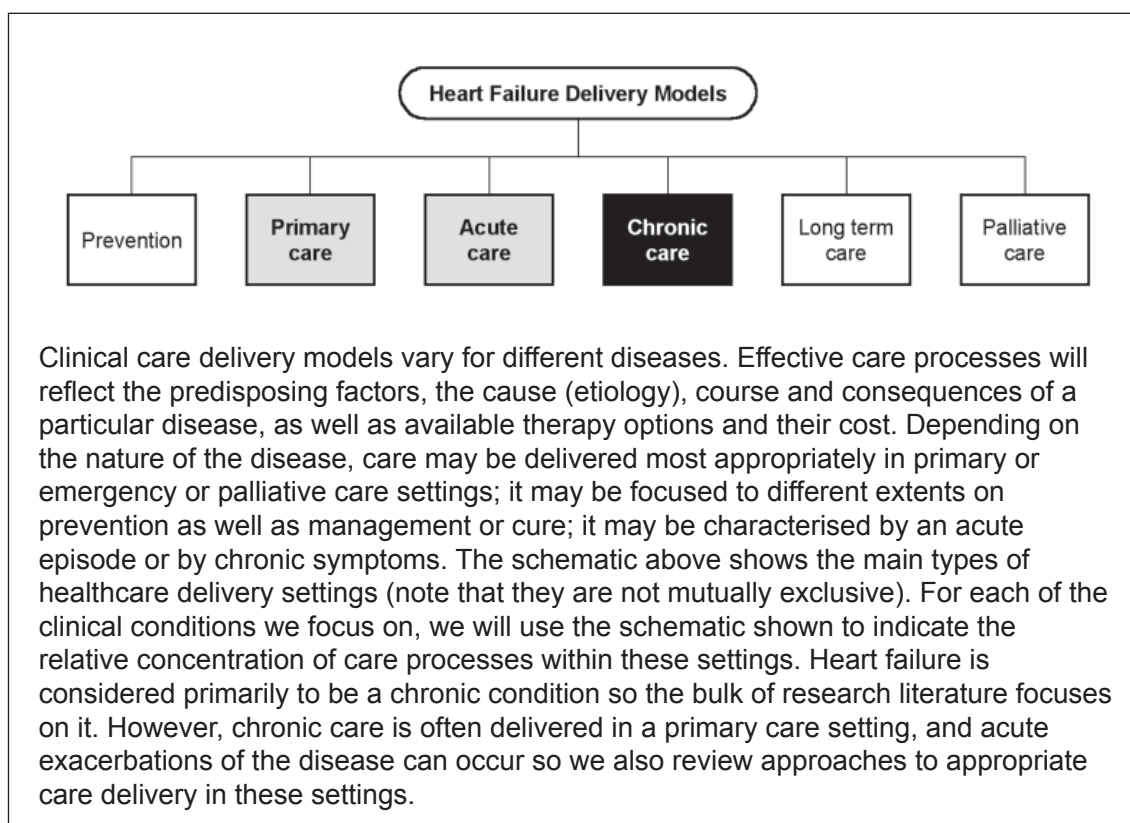
**Figure 1: Quality Enhancing Interventions – major themes**



The findings will form the basis of a searchable resource that will allow decision-makers to find relevant research evidence on particular interventions to improve quality and the context in which they have been implemented, and to access information on different approaches applied to a particular disease or population group.

Within each of the major themes we are developing subcategories and clusters of specific interventions to build a taxonomy of QEIs. Figure 2 illustrates this for the Clinical Care Delivery Models and highlights the focus areas for this report.

**Figure 2: Continuum of healthcare delivery**



Clinical care delivery models vary for different diseases. Effective care processes will reflect the predisposing factors, the cause (etiology), course and consequences of a particular disease, as well as available therapy options and their cost. Depending on the nature of the disease, care may be delivered most appropriately in primary or emergency or palliative care settings; it may be focused to different extents on prevention as well as management or cure; it may be characterised by an acute episode or by chronic symptoms. The schematic above shows the main types of healthcare delivery settings (note that they are not mutually exclusive). For each of the clinical conditions we focus on, we will use the schematic shown to indicate the relative concentration of care processes within these settings. Heart failure is considered primarily to be a chronic condition so the bulk of research literature focuses on it. However, chronic care is often delivered in a primary care setting, and acute exacerbations of the disease can occur so we also review approaches to appropriate care delivery in these settings.

## Methods

We used a 'best evidence' approach to conduct our literature review. We focused primarily on evidence from review articles and guidelines issued by national professional organisations. We conducted electronic searches of MEDLINE<sup>®</sup>, focusing on articles classified as 'review' articles; we included systematic evidence reviews issued by the Cochrane Collaboration. We conducted our searches using a series of steps to identify articles related to the following four main topic areas: heart failure, health systems, healthcare quality and healthcare outcomes. Search strategies are provided in the full report. The review includes research designs ranging from systematic reviews, randomised controlled trials and quasi-experimental studies through to observational studies. Broad inclusion criteria were adopted because of the methodological challenges inherent in assessing organisational and delivery models for chronic illness in general and heart failure in particular.

## Findings

As indicated in Figure 2, this review focused primarily on three areas related to the organisation and delivery of healthcare for patients with heart failure:

- adequate diagnosis so that appropriate treatment can be initiated
- chronic care management
- inpatient treatment for acute exacerbations.

The evidence is summarised in Table 1 below.

**Table 1: Summary of evidence – healthcare delivery models for heart failure**

| Area of focus   | Summary of evidence   |
|---|---|
| Adequate diagnosis so that appropriate treatment can be initiated | <ul style="list-style-type: none"> <li>• Evidence of the effectiveness of open access to echocardiography is limited.</li> <li>• Evidence supports the use of an algorithm for heart failure investigation that uses less expensive tests, such as electrocardiogram and/or blood tests of natriuretic peptides, as a means of triaging patients who need an echocardiogram.</li> </ul>   |
| Chronic care management   | <ul style="list-style-type: none"> <li>• The extant evidence on the effectiveness of disease management in heart failure programmes is mixed.</li> <li>• The evidence supports multidisciplinary management and multifaceted interventions; however, there is no conclusive evidence about how to organise the delivery of these programmes.</li> <li>• There is some evidence to suggest that, compared with general practitioners (GPs), cardiologists provide care that is more consistent with guidelines and have better patient outcomes. This is particularly the case for the likelihood of patients receiving ACE inhibitors and beta blockers.</li> </ul> |

Table continues on next page...



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|   |   |
|---|---|
| Chronic care management continued           | <ul style="list-style-type: none"><li>• Chronic care management activities can be delivered effectively by nurses with advanced training and support and back-up from physicians.</li><li>• The evidence supports the delivery of chronic care interventions in multiple ways including specialty clinics, home-based interventions and disease management programmes; no one model emerged as superior.</li><li>• The evidence suggests that chronic care management can be provided in a GP's office with the support of a nurse specially trained to monitor these patients.</li><li>• There is some evidence that suggests that telemonitoring may be as effective as, or more effective than, other disease management programmes for decreasing patient risk of hospitalisation and increasing quality of life. Additional research is needed to fully assess the value of telemonitoring for improving patient outcomes.</li></ul> |
| Inpatient treatment for acute exacerbations | <ul style="list-style-type: none"><li>• Evidence supports transitional care, begun during the hospital stay and continuing into the community, delivered by an advanced practice nurse; it can reduce length of hospital stay and risk of readmission.</li><li>• The evidence supports starting care management strategies during the inpatient hospital stay to lower the risk of readmission.</li></ul>   |

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# I. Introduction and methods

Heart failure is an increasingly prevalent chronic condition that presents multiple challenges to older individuals, their families and the healthcare delivery system. It is a significant cause of morbidity and mortality for older adults in Western countries (Nieminen and Harjola, 2005; Arnold *et al*, 2006) including the United Kingdom (Davies *et al*, 2001; British Heart Foundation, 2006). As in most developed countries, the ageing of the population is one of the underlying causes of the increase in the prevalence of this condition.

**Heart failure** is the term used to describe the symptoms and signs that occur if the heart becomes less efficient at pumping blood around the body, either at rest or during activity. Heart failure may be the result of damage to the heart muscle. The damage is most typically caused by a heart attack. Heart failure can also be caused by conditions that put an extra workload on the heart. The heart may have coped with this extra workload for years before heart failure occurs. These conditions include high blood pressure (hypertension), anaemia, diseased heart valves, thyroid gland disease or excessively slow or fast heart rate (British Heart Foundation, 2006).

Heart failure represents a serious health system challenge. It accounts for 1 million inpatient days (2 per cent of all National Health Service [NHS] inpatient bed days) and 5 per cent of all emergency medical admissions to hospital (The National Collaborating Centre for Chronic Conditions, 2003). Hospital admissions for heart failure are expected to rise by 50 per cent over the next 25 years largely because of the ageing of the population and the accompanying increase in the underlying causes of heart failure such as coronary heart disease (CHD). Patients with heart failure tend to have frequent and prolonged hospital admissions. As a result, caring for these patients is costly, with estimates of the annual cost of heart failure to the NHS ranging from £400m (Cowie, 2002) to £716m (The National Collaborating Centre for Chronic Conditions, 2003), or around 1.8 per cent of the total NHS budget; much of this figure is attributed to the cost of hospitalisation (The National Collaborating Centre for Chronic Conditions, 2003).

The underlying causes of, and effective treatments for, heart failure are well understood. This information has underpinned the development of multiple evidence-based guidelines for the treatment of this serious condition (Hunt, 2005; Arnold *et al*, 2006; Swedberg *et al*, 2005). Nevertheless, heart failure continues to cause significant morbidity and mortality, quite apart from substantial direct healthcare spending. The imbalance between knowledge of heart failure treatment and effective delivery of guideline-concordant care suggests what Woolf and Johnson characterise as a lack of 'fidelity' in the heart failure care delivered; fidelity in this context refers to 'the extent to which the system provides patients the precise interventions they need, delivered properly, precisely when they need them' (Woolf and Johnson, 2005, p 545).

In this report, we focus our review on the evidence related to healthcare delivery models that can support effective diagnosis, treatment and management of heart failure. The emphasis, therefore, is not on amassing evidence about effective clinical treatments per se but rather on evidence regarding health system delivery modalities related to the care of heart failure patients.

## Background

Recent estimates of the prevalence of heart failure in the United Kingdom are as high as 900,000 people currently diagnosed with heart failure and nearly as many who have damaged hearts but are not yet symptomatic (The National Collaborating Centre for Chronic Conditions, 2003). The incidence and prevalence of heart failure increase rapidly with age; the mean age of the heart failure population is 74 years (Nieminen and Harjola, 2005). Approximately 6 to 10 per cent of people older than 65 years of age have heart failure and nearly 80 per cent of patients admitted to hospital with a diagnosis of heart failure are older than 65. These statistics demonstrate that heart failure is prevalent among older adults and that the increased societal burden resulting from heart failure is partly attributable to the success of treating coronary artery disease and the increased likelihood that patients with coronary artery disease will survive into old age.

### National Service Framework: Service models for heart failure

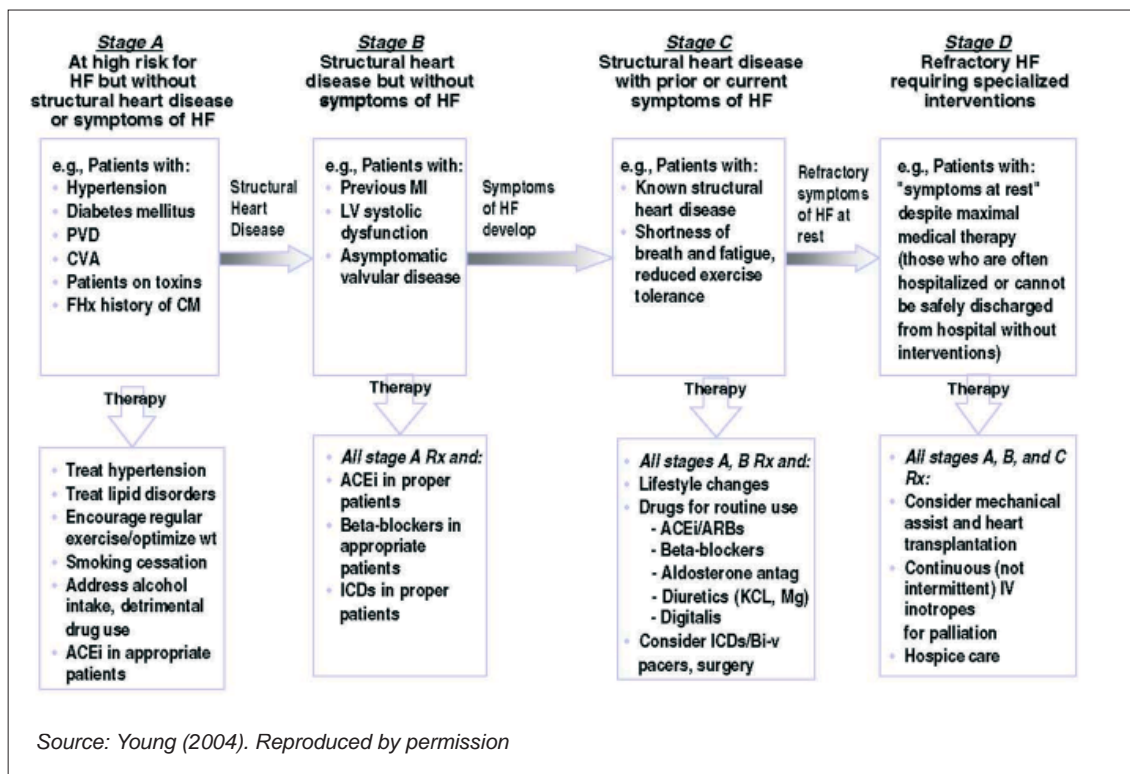
Heart failure is a complex cardiac condition encompassing several underlying aetiologies and co-morbidities (Nieminen and Harjola, 2005). The chronic nature of heart failure requires ongoing monitoring and treatment of patients. The publication in March 2000 of the *National Service Framework for Coronary Heart Disease* (Department of Health, 2000) set national standards for improving the diagnosis and treatment of heart failure (Gnani *et al*, 2004). Because general practitioners (GPs) in primary care practice treat the majority of patients with heart failure and act as gatekeepers to hospital care for patients who require acute care, they play a key role in ensuring that the framework standards are met.

The service models for primary care teams and hospitals as set by the national service framework (NSF) include a systematic approach that:

- identifies people at high risk of heart failure
- assesses and investigates people with suspected heart failure
- provides and documents the delivery of appropriate advice and treatment
- offers regular reviews to people with established heart failure.

This approach is consistent with the emphasis of the American Heart Association (AHA)/ American College of Cardiology (ACC) heart failure diagnosis and treatment guidelines (see Figure 3). These guidelines introduce a staging system that also considers the population at risk of developing heart failure (Young, 2004). Conditions such as hypertension and atherosclerotic disease among ageing patients, as well as obesity and diabetes, place individuals at risk.

Figure 3: Staging system for heart failure



Since the publication of the CHD NSF in 2000, there is evidence that the delivery of healthcare services for management of heart failure has improved (Sutherland and Leatherman, 2006). However, the level of improvements varies across different services provided; therefore, additional efforts are needed to meet all of the NSF goals. In particular, the quality of care for CHD provided to men is generally superior to that received by women. For example, a cross-sectional study of 26 general practices in the Kent, Surrey and Sussex Primary Care Research Network (Majeed *et al*, 2005) has showed that blood pressure and smoking status are generally well documented (92 per cent of men and 90 per cent of women; 84 per cent of men and 77 per cent of women, respectively). In addition, 85 per cent of men and 84 per cent of women received an influenza immunisation. The same study found that only 17 per cent of men and 11 per cent of women had undergone an echocardiogram and only 76 per cent of men and 68 per cent of women were using an angiotensin-converting enzyme inhibitor (ACE-I) to manage their heart failure.

Heart failure is a highly studied area of clinical medicine. Physicians and other clinicians can consult numerous treatment and management guidelines; for example, the European Society of Cardiology, the Canadian Cardiovascular Society, the American College of Cardiology and the American Heart Association recently produced comprehensive guidelines (Hunt, 2005; Arnold *et al*, 2006; Swedberg *et al*, 2005). However, many of the treatment guidelines focus on the pharmacological therapies (Cowie, 2002), which are a necessary but insufficient approach to the care and management of patients with this condition.

Comprehensive healthcare delivery models are organised around four main elements of healthcare service and along various points in the continuum of the healthcare system:

- care processes – these are the activities and interventions conducted to investigate, diagnose and treat health conditions. Components of the care process can include the following:

- prescribing and/or dispensing medication
  - counselling, which can be oral or through printed, video or computer-based messages
  - monitoring
  - lifestyle modifications, such as weight loss and exercise.
- workforce – this category encompasses individuals involved in delivering healthcare. Examples include physicians, nurses, pharmacists, social workers, technicians and even patients themselves who are increasingly called on to engage in self-care activities to prevent or manage health conditions.
  - facilities – these are settings in which healthcare activities take place, such as hospitals, emergency departments, physicians' offices or specialised clinics.
  - equipment – these are tools and devices that healthcare professionals use to conduct care processes, such as a stethoscope to monitor breath sounds, diabetic test strips to monitor blood sugar, scales to measure weight and even telephones to contact patients for appointment reminders or to provide advice for self-care activities.

**The continuum of care is composed of the following:**

- preventive care – includes the management of risk factors among those with high risk in the general population
- primary care – includes diagnosis and treatment of early risk factors of disease as well as management of chronic illness
- acute care – includes treatment for acute exacerbation and relapse
- long-term care – includes community-based or institutional social and medical support of frail and chronically ill individuals who are dependent on others to help them perform activities of daily living
- palliative care – includes support for managing pain and discomfort at the end of life.

Chronic illness care traverses this continuum of healthcare services because chronic conditions (such as heart failure) are characterised by three different needs, often addressed in different settings:

1. monitoring of symptoms in the primary care setting
2. effective treatment of exacerbations in the acute care setting
3. long-term care due to increased frailty and palliative care at the end of life.

This review focuses on healthcare delivery models related to the diagnosis and management of heart failure in the primary and acute care settings. We are not dealing here with long-term or palliative care or with primary prevention. For example, a primary care provider might diagnose heart failure and take charge of co-ordinating and delivering care to manage the patient's symptoms so as to delay or prevent exacerbations of the disease. Because of the chronic nature of this disease, the bulk of the evidence cited in this report addresses the care processes, personnel, facilities and equipment used to provide chronic care support for patients with heart failure.

## Methods

The organisation and delivery of healthcare services are complex concepts that are challenging to define; the delivery system includes a variety of personnel, processes and infrastructure elements. Neither the organisation nor delivery of healthcare is well indexed in existing reference databases of medical literature, such as MEDLINE®. Therefore, we needed to develop a strategy that used a variety of terms related to healthcare systems, quality, processes and outcomes to find relevant literature that would enable us to identify evidence of effective models of healthcare delivery for addressing heart failure.

### Literature search strategy

**Table 2: Topic areas and examples of associated MeSH terms**

| Topic area          | Examples of MeSH terms searched (*text word)   |
|---------------------|--|
| Heart failure       | heart failure, congestive<br>chronic heart failure*<br>heart failure*  |
| Health system terms | disease management<br>community health services<br>delivery of healthcare<br>program evaluation<br>regional health planning<br>emergency medicine  |
| Quality             | quality assurance, health care<br>quality indicators, health care<br>health care quality, access and evaluation<br>quality of life<br>process assessment (health care)<br>guideline adherence<br>continuity of patient care<br>information systems |
| Outcomes            | health status<br>outcome assessment, health care<br>mortality<br>morbidity<br>self care  |

We used a 'best evidence' approach to conduct our literature review. We focused primarily on evidence from review articles and guidelines issued by national professional organisations. We conducted electronic searches of MEDLINE®, focusing on articles classified as 'review' articles; we included systematic evidence reviews issued by the Cochrane Collaboration. We limited our searches to articles in English published since 1995 that focused on adults aged 19 and older.

We conducted our searches using a series of steps to identify articles related to the following four main topic areas: heart failure, health systems, healthcare quality and healthcare outcomes. Table 2 lists each topic area and gives examples of the associated Medical Subject Heading (MeSH) terms or text words employed in the literature search. A full list of

MeSH terms and text words used to conduct the literature search is provided in Appendix A. This search strategy was also employed with the MEDLINE® and CINAHL databases to identify randomised controlled trials (RCTs) since 2003 that may not have been included in the review articles published to date.

In addition to these main searches, several ad hoc searches of RCTs were conducted to gather additional evidence about delivery models related to care of acute heart failure, diagnosis of heart failure, use of registries to organise care for heart failure and telemonitoring support for heart failure management.

## **Article selection and review**

Article titles and abstracts for 318 review articles and 155 RCTs were reviewed independently by 2 report authors. Based on the title/abstract review, we retained approximately 107 articles obtained electronically or by interlibrary loan. These articles were reviewed independently by 2 report authors and 51 of these were abstracted and included in this review.

## **Quality and strength of evidence**

The quality of the evidence reviewed was variable and often incomplete. We were investigating comprehensive healthcare delivery models for heart failure, but this is a complex topic that is not generally studied in its totality. Rather, studies often test specific elements of a healthcare delivery model. Further, several of the studies that examined models of care, such as disease management programmes, did not clearly define details of the delivery model.

Because research testing healthcare delivery models is often done with designs other than those used for RCTs, we discuss findings from reviews that included a variety of study designs, RCTs, observational studies or both. Most review articles documented their literature search strategies and inclusion and exclusion criteria. Several review articles employed multiple independent reviewers and grading systems to characterise the quality of studies reviewed.

The evidence base for healthcare delivery models to address chronic illnesses, and in particular heart failure, is evolving, as indicated by the significant limitations discussed in the conclusion of this report. Most notably, additional research is needed that includes larger, more diverse populations and healthcare settings, supported by sophisticated information systems that can accurately capture testable particulars of the interventions delivered, and rigorous documentation of 'usual care' received by comparison groups.

## **Format of the report**

Chapter 2 presents the available evidence for the organisation and delivery of services to patients with heart failure. We discuss the delivery of services required for the diagnosis of heart failure, followed by healthcare practices for the management of this chronic condition. We then present evidence related to healthcare provided to address acute exacerbations of heart failure.

The evidence is presented in brief summaries that provide details of research design and findings drawn from international literature. We also provide a summary of independent reviews of the quality of each study conducted by the Centre for Reviews and Dissemination (CRD), when available. Within each section of the report, we present evidence in the order of most to least rigorous study designs based on the following classification:

- Cochrane systematic reviews
- meta-analyses
- systematic reviews (that is, articles that include detailed information about search strategy and criteria for inclusion and exclusion from the review)
- randomised controlled trials (RCTs)
- observational studies
- non-systematic reviews (that is, narrative synthesis of the professional literature with no information about criteria for selection in the review).

Several methodological challenges limited our ability to deliver unequivocal evaluations of the effectiveness of service delivery models:

- small sample sizes often associated with intervention studies
- lack of evidence that links specific aspects of modifications in the care processes to improvements in health outcomes
- issues of generalisability, as many of the studies are conducted in academic medical centres
- lack of detail regarding the specifics of a delivery system intervention
- variability in outcome measures, particularly for impact on patients, making it difficult to compare results across studies.

Delineating aspects of healthcare delivery innovations to inform recommendations for health system redesign is not a straightforward process. For many interventions, evidence is insufficient for recommending a particular approach. We review weaknesses and gaps in the evidence base that could be used to influence healthcare delivery for heart failure; we also present evidence for areas of promising practices for delivering services to this chronically ill population.



## II. Healthcare delivery models for heart failure

### Diagnosis of heart failure

#### Disease course and recommended care guidelines

Primary care for heart failure includes timely and appropriate diagnosis and management of the chronic nature of heart failure following diagnosis. Symptoms such as fatigue, shortness of breath, exercise intolerance and fluid retention make doctors suspect heart failure (Beers *et al*, 2003).

#### **B-type natriuretic peptide blood test**

B-type natriuretic peptide (BNP) is a protein secreted from the lower chambers of the heart in response to changes in pressure that occur when heart failure develops and worsens. The level of BNP in the blood increases when heart failure symptoms worsen, and decreases when the heart failure condition is stable. The BNP level in a person with heart failure – even someone whose condition is stable – is higher than in a person with normal heart function.

The most widely used classification scheme of heart failure symptoms is from the New York Heart Association (NYHA); it classifies patients into one of four classes (Table 3). Patients in NYHA classes I and II benefit from early diagnosis so that early intervention can prevent development of classes III and IV symptoms. Early diagnosis requires a combination of expertise on the part of a primary care clinician, appropriate referral to a specialist and easy availability of certain diagnostic tests including x-ray, electrocardiography and a B-type natriuretic peptide (BNP) blood test (see box on BNP). Effective treatment of heart failure may prolong life as well as increase the quality of life for the heart failure patient.

**Table 3: New York Heart Association classification of heart failure symptoms**

| Class | Symptoms  |
|-------|---|
| I     | No physical limitations. Ordinary physical activity does not cause fatigue, breathlessness or palpitation.  |
| II    | Slight limitation of physical activity. Such patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitations, breathlessness or angina. |
| III   | Marked limitation of physical activity. Less than ordinary physical activity will lead to symptoms.   |
| IV    | Inability to carry on any physical activity without discomfort. Symptoms are present even at rest.  |

Given the chronic nature of heart failure, patients' functional class tends to deteriorate over time. However, the severity of symptoms and the trajectory of decline can fluctuate, or even slow considerably, with guideline-concordant care. Although careful attention to symptoms is a hallmark of good primary care, symptoms alone cannot be relied on to make the diagnosis, which depends on a combination of an assessment of symptoms and tests. Cleland (2002) suggests that as many as 80 per cent of heart failure diagnoses occur in hospital following an acute episode of an underlying condition. The remaining 20 per cent of patients are

diagnosed in a primary care or community setting. This suggests the need for the availability of adequate diagnostic technology in both inpatient and community settings.

### ***Guidelines for diagnosis of heart failure***

In addition to monitoring patients' signs and symptoms, the most useful test for diagnosing heart failure is provided by echocardiography, which is recommended by the current guidelines issued by the European Society of Cardiology, the Canadian Cardiovascular Society, the American College of Cardiology and the American Heart Association, the CHD NSF and the clinical guideline for chronic heart failure issued by the then National Institute for Clinical Excellence (NICE) in 2003 (Swedberg et al, 2005; Arnold et al, 2006; Hunt, 2005; Department of Health, 2000; The National Collaborating Centre for Chronic Conditions, 2003).

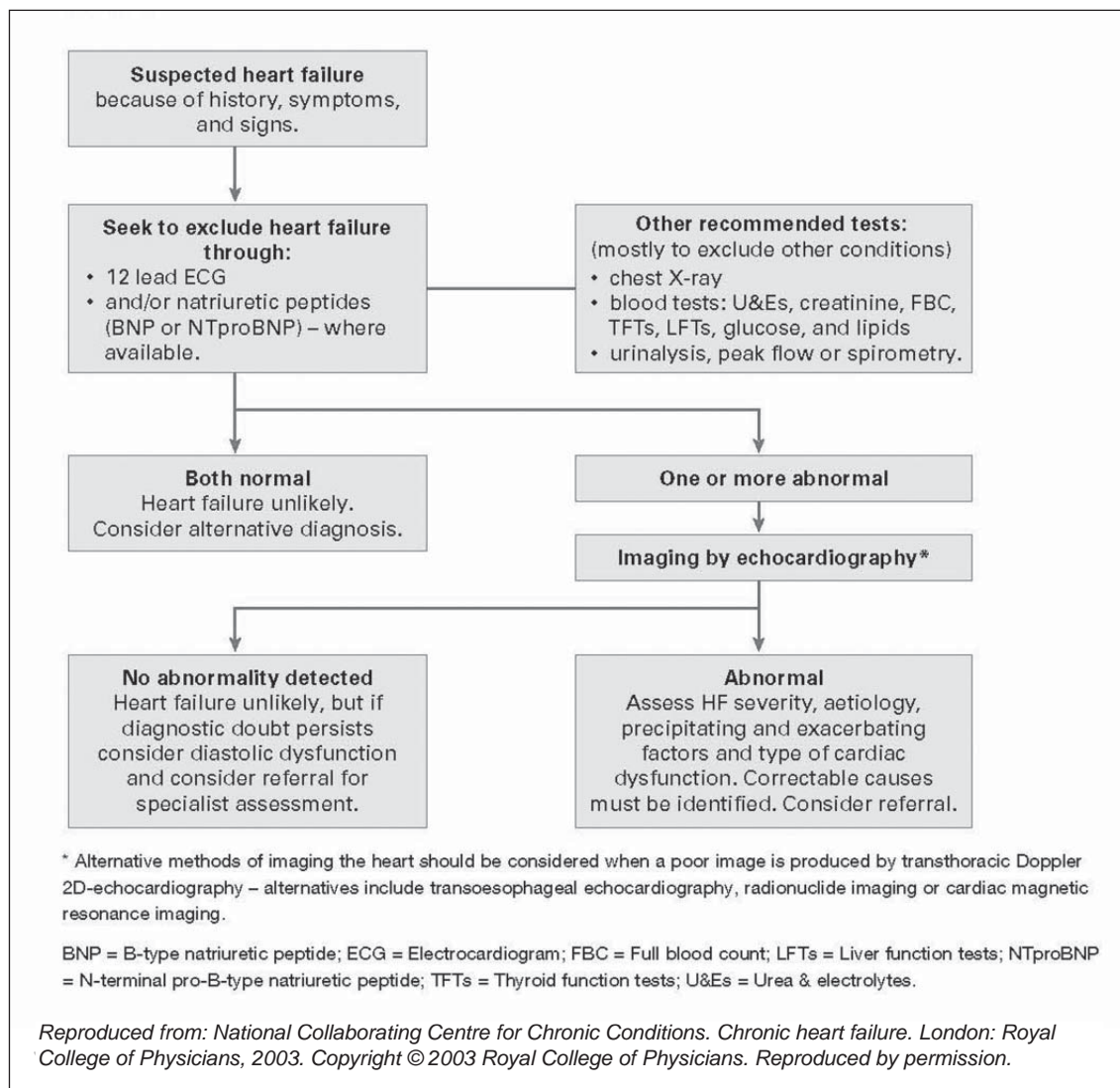
For example, the NSF recommends that 'Doctors should arrange for people with suspected heart failure to be offered appropriate investigations (for example, electrocardiography, echocardiography) that will confirm or refute diagnosis [of heart failure]' (The National Collaborating Centre for Chronic Conditions, 2003, p 46). The guidelines do not specify where echocardiography should be done; rather they note that the test can be provided in specialist heart clinics, by cardiologist outpatient care and by open access to echocardiography from primary care.

In contrast, the NICE guidelines and the European Society of Cardiology guidelines both include algorithms for the investigation of heart failure (see Figure 4). Both reserve the use of echocardiography for individuals who have abnormal results on electrocardiogram (ECG), x-ray and/or a BNP blood test (The National Collaborating Centre for Chronic Conditions, 2003; Swedberg et al, 2005).

### ***Challenges encountered in diagnosing heart failure***

An **echocardiogram** (also called an echo) is a type of ultrasound test that uses high-pitched sound waves to take moving pictures of a heart that can be seen on a video screen. The device picks up echoes of the sound waves as they bounce off the different parts of the heart. The test shows the size and shape of the heart, the overall level of heart functioning, weakness in a wall or section of heart muscle, heart valve performance and presence of blood clots (WebMD, 2006; American Heart Association, 2004).

Management of heart failure begins with an accurate diagnosis. Studies have shown that the accuracy of diagnosis by clinical means alone is often inadequate (for example, Swedberg *et al*, 2005), particularly among women, elderly and obese patients. To optimise the treatment of heart failure, uncertainty in diagnosis must be addressed (Swedberg *et al*, 2005).

**Figure 4: Algorithm summarising recommendations for the diagnosis of heart failure**

Despite clear, well-established recommendations, the percentage of people suspected of having heart failure who receive echocardiography investigation (see box on echocardiograms) remains relatively low. An observational study published in 2004 with data from 2 computerised general practices in south London found that only 38 (42 per cent) of 90 patients diagnosed with heart failure had undergone echocardiography according to information obtained from medical record review (Gnani et al, 2004). The primary reason cited for this gap in appropriate care is limited access to echocardiography services. Echocardiography is an expensive service that requires skilled staff to interpret results. Typically, GPs are required to refer patients to specialists to conduct this service due to the complexities involved in reviewing the images produced.

Several surveys of physicians in Europe indicate that they often encounter challenges in diagnosing heart failure owing to lack of access to echocardiography (Hobbs, 2002; Khunti et al, 2002; Hickling et al, 2001; Gnani et al, 2004; Leslie et al, 2005). For example, a series of semi-structured interviews with GPs and practice managers in south London found that GPs report difficulty confirming heart failure diagnoses. The reasons cited were largely lack of timely access to echocardiography (or any access in some regions) fuelled by an inadequate supply of echocardiography technicians (Gnani et al, 2004). A more recent survey of GPs in the Lothian health board area in Scotland further confirmed the need for

better access to echocardiography and the fact that use of other methods often results in inaccurate diagnoses, both lack of findings in the presence of disease and diagnosis of heart failure in the absence of the condition (Leslie et al, 2005).

There are two delivery system solutions for providing diagnostic services for patients with symptoms of heart failure:

- open access to echocardiography services for GPs, that is, where GPs can order echocardiograms directly without referral to a specialist
- implementation of an algorithm for heart failure investigation that promotes the use of less expensive tests, such as electrocardiogram and/or blood tests of natriuretic peptides before performing an echocardiogram.

Below we provide evidence related to the effectiveness of each of these delivery system solutions. The approach to diagnosis of heart failure has changed over the past ten years, leading some to question the diagnosis of heart failure among patients identified in GP registries (The National Collaborating Centre for Chronic Conditions, 2003). The guidelines recommend the use of less costly screening tests to exclude patients with symptoms resulting from causes other than heart failure and reserving the echocardiography for those with suspected heart failure. Evidence of the effectiveness of open access to echocardiography is limited: we found no RCTs examining the impact of this healthcare delivery option. Implementation of an algorithm for heart failure investigation that promotes use of less expensive tests, such as electrocardiogram and/or blood tests of natriuretic peptides prior to performing an echocardiogram, may be less costly for triaging patients suspected of having heart failure. Thus, the evidence is not clear on whether to make echocardiography openly accessible to GPs.

#### *Evidence: Open access echocardiography*

Summary of evidence: Evidence of the effectiveness of open access to echocardiography is limited. We found no RCTs examining the impact of this healthcare delivery option.

Several observational studies were conducted in the mid-1990s to assess utilisation of echocardiography under conditions of open access to GPs (Francis *et al*, 1995; Murphy *et al*, 1996).

Francis *et al* (1995) conducted an observational study of 259 consecutive patients referred to an open echocardiography service at a regional cardiology centre in Edinburgh and found that 88 per cent of referrals to the service were clinically appropriate. Further, the authors suggested that open access to echocardiography is cost-effective because the service resulted in changes in treatment for 70 per cent of patients examined. These changes encompassed both initiation of treatment for previously undiagnosed heart failure and cessation of pharmacotherapy for patients suspected of having heart failure and whose diagnosis was not confirmed by echocardiography. The authors noted that the large number of referrals to the service provides evidence of high provider satisfaction. This article, published in the *British Medical Journal*, generated 9 editorial responses, including 6 that questioned the conclusions of the authors, signifying the controversial nature of this issue. Of note, one response commended the fact that GPs were required to attend a training session prior to gaining access to the echocardiography service. However, the uptake of the training intervention was low: only 93 of 550 invited physicians attended the education session and participated in the intervention. The evidence is inconclusive as to whether rapid access to a clinical assessment by a cardiology specialist would be more effective than open access to echocardiography by GPs.

Similarly, Murphy *et al* (1996) published a brief report describing an observational study of open-access cardiography among physicians in 5 general practices in Darlington in Durham County, UK. The purpose of the intervention was to initiate therapy with ACE inhibitors for patients previously diagnosed with heart failure who were taking a diuretic. Of 250 patients who underwent echocardiography, 49 were diagnosed with heart failure and, within 2 months of the test, approximately 75 per cent of these individuals were using an ACE inhibitor (Murphy *et al*, 1996).

*Evidence: Use of echocardiography following less costly screening to diagnose heart failure*

Summary of evidence: Implementation of an algorithm for heart failure investigation that promotes use of less expensive tests, such as electrocardiogram and/or blood tests of natriuretic peptides, prior to performing an echocardiogram may be a cost-effective strategy for triaging patients suspected of having heart failure.

Shah *et al* (2004) recommend reserving echocardiography for patients who have indications of heart failure based on findings from ECG and chest radiograph in an observational study. Logistic regression using data from 963 patients who underwent 12-lead ECG, chest x-ray and echocardiography at a hospital-based heart failure service in the United Kingdom between 1994 and 2001 revealed 4 factors that significantly predicted heart failure: abnormal ECG, abnormal enlargement of the heart observed via chest radiograph, male sex and diabetes. Because only 30.8 per cent of patients suspected of heart failure based on signs and symptoms, such as shortness of breath, were found to have the condition, the authors recommended screening for heart failure before starting more expensive diagnostics, such as echocardiography.

## Chronic care for heart failure

### Disease course and recommended care guidelines

Heart failure has been described as a 'disease of recidivism' (Peacock, 2005), one that is characterised by clinical exacerbations that result in acute need for emergency or inpatient care. Patients with heart failure typically experience a pattern of deterioration followed by stabilisation; however, their overall course is that of a 'steadily deteriorating clinical pattern' (Peacock, 2005). The goal of care for patients with this disorder is to prolong periods of stabilisation and prevent periods of exacerbations; this would result in a better quality of life for the patient and more efficient use of resources for the healthcare delivery system.

A diagnosis of heart failure often requires patients to make significant adjustments in lifestyle. Patients need to carefully adhere to medication regimens and to perform close self-monitoring of symptoms; they may also need to make marked changes in diet and exercise. From the patient's perspective, successful symptom control, prevention of acute exacerbation and maintenance of function require active participation in the disease management process. From the perspective of the delivery of care, successful management requires not only the provision of pharmacological therapy but also, particularly for NYHA classes III and IV, intensive follow-up, close monitoring of symptoms by health professionals and sustained efforts to improve patient compliance. The current state of the research literature, while clearly providing evidence supporting the need for chronic care management of heart failure, does not support a single, specific healthcare delivery model. Some critical elements of the care process do need to be a consistent part of chronic care management.

However, a variety of approaches can be implemented so that guideline-concordant care can be delivered successfully.

Care for the chronically ill can be improved if the delivery system adopts an orientation that emphasises comprehensiveness of care. One of the underlying causes of the gaps in quality of care for the chronically ill has been attributed to a lack of co-ordination and poor organisation. The current care system was designed to respond rapidly and efficiently to acute illness and injury with a focus on the immediate problem and a view of the patient's role as one who is largely passive.

By contrast, chronic illness presents a set of challenges to the patient and their family that includes dealing with symptoms, disability, emotional impact, complex medication regimens and lifestyle adjustments (Wagner et al, 2001). The Chronic Care Model developed by Wagner and colleagues is an approach to addressing the needs for quality improvement and disease management activities for the chronically ill (Wagner et al, 2001). The model predicts that improvement in its six interrelated components – self-management, clinical information systems, delivery system redesign, decision support, healthcare organisation and community resources – can produce system reform in which informed, activated patients interact with a prepared and proactive healthcare team (Bodenheimer et al, 2002).

Designing a delivery system that considers the ongoing needs of chronically ill patients necessitates a change in approach, one that includes the provision of self-management support (Coulter and Ellins, 2006). Effective treatment for these patients involves often complex drug management, time-consuming patient education and regular interaction with a primary care provider. The consequences of not providing careful management of patient status and symptoms include excessive use of emergency and hospital services; for example, as many as 50 per cent of heart failure inpatient admissions may be preventable (Ojeda et al, 2005).

Heart failure patients typically have multiple co-morbid medical conditions, disabling symptoms, complex medical regimens and limited self-management skills. Thus, careful attention to their comprehensive care management needs can improve patient well-being and prevent unnecessary and expensive use of inpatient resources. Many of the models of care reviewed in the following section address the need for ongoing services that combine the following elements in various ways: patient and family education, patient and family support, medication management, ongoing monitoring, use of guideline consistent protocols

and registries. Table 4 provides an overview of the current guidelines for care management of heart failure.

**Table 4: Guidelines for chronic care for heart failure**

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| <p><b>Who should deliver care?</b></p> | <ul style="list-style-type: none"> <li>• ACC/AHA guidelines concluded that evidence is insufficient to recommend whether care for heart failure patients should be delivered by primary care physicians or cardiologists. Limited evidence suggested that cardiologist care results in better patient outcomes; however, the guidelines also suggested that 'primary care physicians with knowledge and experience in heart failure should be able to care for most patients with uncomplicated heart failure' (Hunt, 2005, p e56). Further, the authors suggested that optimal care is likely to be delivered by a team that includes both a primary care physician and a cardiologist (Hunt, 2005).</li> <li>• The NSF and the Canadian Cardiovascular Society guidelines suggest that patients with heart failure should have access to 'multidisciplinary support in the community' including home visits, and that heart failure clinics may be an effective way to deliver ongoing support for heart failure patients. In addition, the framework suggests that care provided by general practice physicians should be informed by evidence-based practice protocols (Department of Health, 2000; Arnold <i>et al</i>, 2006).</li> </ul> |
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|---|--|
| <p><b>How should care be delivered?</b></p>   | <ul style="list-style-type: none"> <li>• Patient education to support self-management, including recognition of early warning signs of complications, weight monitoring, low-sodium diets, compliance with medication regimen and appropriate use of diuretics (The National Collaborating Centre for Chronic Conditions, 2003; Arnold <i>et al</i>, 2006; Swedberg <i>et al</i>, 2005; Hunt, 2005).</li> <li>• Patient monitoring on a regular basis to detect changes in heart functioning, need for adjustments in medication regimen and need for social support services (The National Collaborating Centre for Chronic Conditions, 2003; Arnold <i>et al</i>, 2006; Swedberg <i>et al</i>, 2005; Hunt, 2005).</li> <li>• The NSF standards include a goal for each primary care team to have a practice-based registry to inform care of patients with CHD (Hunt, 2005).</li> <li>• The Canadian Cardiovascular Society recently published recommendations for the diagnosis and management of heart failure that include guidance related to exercise training (Arnold <i>et al</i>, 2006).<sup>a</sup> Patients with stable heart failure symptoms and impaired left ventricular systolic function should engage in regular physical activity. Providers should consider 3 to 5 exercise sessions per week lasting 30 to 45 minutes for individuals with stable NYHA class II to III heart failure and left-ventricular ejection fraction less than 40 per cent.<sup>b</sup></li> <li>• Individualised exercise training may initially be given by supervised trainers in a setting with external defibrillators when these resources are available. The authors offer the practical tip that providers should consider referral to a cardiac rehabilitation programme for all stable patients with NYHA class I to III heart failure.<sup>c</sup></li> <li>• The 2005 ACC/AHA practice guidelines recommended exercise training for stable outpatients with chronic heart failure; however, they did not comment on the personnel, facilities or equipment that should be used to deliver this intervention (Hunt, 2005). The European Society of Cardiology includes a similar recommendation in its 2005 guideline update (Swedberg <i>et al</i>, 2005).</li> </ul> |
| <p><b>Where should care be delivered?</b></p> | <ul style="list-style-type: none"> <li>• The Canadian Cardiovascular Society recommendations suggest that specialised hospital-based clinics should be developed to provide support for patients with heart failure.<br/><sup>d</sup> Further, the society recommended that resources for heart failure management should be available across the continuum of outpatient care delivery services<sup>e</sup> (Arnold <i>et al</i>, 2006; Fonarow and Corday, 2004).</li> </ul>   |

<sup>a</sup>Evidence for each recommendation was categorised by three classes of recommendation (Class I: evidence or general agreement that a treatment is beneficial, useful and effective; Class II: conflicting evidence about the efficacy of the procedure or treatment; and Class III: general agreement that a treatment is not useful or effective, and may be harmful in some cases). They also specified grade of evidence (from Level A [data derived from multiple randomised clinical trials or meta-analyses] to Level C [consensus of expert opinion or small studies]).

<sup>b</sup>Class IIa, Level B recommendations

<sup>c</sup>Class IIb, Level C recommendations

<sup>d</sup>Class I, Level A recommendation

<sup>e</sup>Class I, Level C recommendation



## Evidence for chronic management of heart failure patients

In presenting the evidence about the chronic management of heart failure patients, this section organises the studies around three questions:

- Who should be delivering care?
- How should care be delivered?
- Where should care be delivered?

Although these questions provide a useful framework, this structure is somewhat constrained in that many studies cited address more than one question. Studies were sorted by the question that seemed to dominate the findings; however, the findings are often relevant to more than one question.

### ***Who should be delivering care?***

*Evidence: Care provided by cardiologists and GPs*

Summary of evidence: The evidence regarding treatment by general physicians versus cardiologists for heart failure is limited and reflects mixed findings.

Some evidence suggests that, compared with GPs, cardiologists provide care that is more consistent with guidelines and have better patient outcomes. This is particularly the case for the likelihood of patients receiving ACE inhibitors and beta blockers. However, the evidence is limited and findings are mixed. Chronic care management activities can be effectively delivered by specialist or advanced practice nurses with support from physicians and other allied health professionals. Ideally, all providers, regardless of specialty, who are treating patients with heart failure should have experience and particular expertise in managing this specific condition.

Go *et al* (2000) systematically reviewed the professional literature to examine the relationship between physician specialty and knowledge, practice patterns and outcomes of patients with coronary disease and heart failure. The 24 articles reviewed focused exclusively on healthcare delivery in the United States and were published between 1984 and 1997. Compared with internists, family physicians and geriatricians, cardiologists were more likely to self-report that they would refer patients for left ventricle function assessment and to prescribe ACE inhibitors for patients with mild cases of heart failure in the absence of symptoms. Overall, patients treated by cardiologists were more likely to receive ACE inhibitors than those treated by generalists; however, this result was statistically significant in only one of the 6 studies that addressed this issue. Similarly, limited evidence from 2 studies indicated that patients treated by generalists are at higher risk of readmission within 6 months of hospitalisation for heart failure. Generalists and specialists had similar knowledge of the recommendations for ACE inhibitors for heart failure. No independent assessment of the quality of the review was found.

Ansari *et al* (2003) observed that 403 patients newly diagnosed with heart failure who were treated by a cardiologist in a staff-model managed care plan in the United States had a lower combined risk of mortality or cardiovascular hospitalisation at 24 months than similar patients treated by primary care physicians, when controlling for patient characteristics. In addition, patients treated by cardiologists were more likely to receive guideline-concordant care, such as assessment of left ventricular function and treatment including ACE inhibitors, beta blockers and digoxin. Using an electronic database, patients were selected for this retrospective cohort study if they had an outpatient encounter with a diagnosis of heart

failure, cardiomyopathy or hypertensive heart disease without evidence of prior service utilisation for these conditions.

Edep *et al* (1997) conducted an observational survey of approximately 1,000 physicians in the United States during 1995 to examine the quality of heart failure care provided by family practice physicians, internists and cardiologists. Multivariate analyses showed that cardiologists were most likely to provide care concordant with the guidelines released in 1994 by the Agency for Healthcare Policy and Research (now Agency for Healthcare Research and Quality) and that internists were more likely to provide guideline-concordant care than family practitioners. Specifically, only 60 per cent of family practitioners prescribed ACE inhibitors for patients with mild to moderate heart failure compared with 71 per cent of internists and 80 per cent of cardiologists.

An observational study conducted in 1996 and 1997 by Sakakibara *et al* (1999) in Japan indicated that outpatient care for stable patients with heart failure should be delivered by a GP. The study followed 63 patients after hospitalisation for heart failure: 31 patients received outpatient follow-up care from a cardiologist whereas 24 patients received care from GPs. Similar to other studies we reviewed, patients cared for by GPs were older, on average, than those under care of a cardiologist; however, the 2 cohorts did not differ significantly in any other way. Patients in both groups were equally likely to receive ACE inhibitors, diuretics and stimulants (if indicated). Patients cared for by cardiologists were significantly more likely to be rehospitalised than those cared for by GPs (that is, 79 per cent compared with 52 per cent). Further, cardiologists' patients were more likely to have multiple hospitalisations during the 6 months following the index admission than those who were treated by a GP (that is, 36 per cent compared with 9.9 per cent). The 2 groups had similar survival rates.

#### *Evidence: Multidisciplinary programmes with physician oversight*

Summary of the evidence: There is strong evidence supporting the benefit of multidisciplinary programmes for the management of heart failure, particularly for the elderly.

Holland *et al* (2005) conducted a meta-analysis of 30 RCTs of multidisciplinary interventions for heart failure management from Europe, the United States, Australia, New Zealand and Argentina. The studies reviewed were conducted between 1993 and 2004 with sample sizes ranging from 71 to 1,518 patients. Interventions that involve a physician and at least one other type of health professional, that is, specialist nurse, pharmacist, dietician or social worker, reduced the risks of all-cause hospitalisation (13 per cent lower risk), heart failure-related admissions (30 per cent) and mortality (20 per cent) compared with individuals receiving usual care.

The authors reported outcomes of interventions classified into the following four types:

- home visits – statistically significantly decreased risk of all-cause and heart failure-related admissions
- telemonitoring – statistically significantly decreased risk of mortality (no data available for hospital admission rates)
- telephone follow-up or educational mailings – trend toward decreased risk of all-cause hospitalisations, statistically significant reduction in heart-failure related admissions and mortality
- hospital or clinic interventions – observed to have no impact on patient outcomes under study.

Finally, the authors noted that the evidence does not support the strategy of primarily targeting interventions to high-risk patients; rather, it suggests a more inclusive focus. No independent assessment of the quality of the review was found.

Philbin (1999) reviewed multidisciplinary programmes for the management of heart failure focusing on interventions lasting 3 months or more that involved physicians working in tandem with nurses. Studies reviewed also had to report observed clinical practices, healthcare charges or costs and clinical outcomes, and include a control group or historical reference sample. This review of 7 studies (6 conducted in the United States and one in Israel) provided strong evidence of the effectiveness of multifaceted disease management programmes for improving functional status and reducing the risk of hospital admission, and weak evidence of healthcare cost savings. Specifically, the various studies reported 14 to 87 per cent decreases in hospital admissions. The authors did not provide statistics to specify the degree of improvement in quality of life in the 2 studies that measured this outcome. The studies reviewed were published between 1983 and 1998 with sample sizes ranging from 15 to 924 patients. An independent assessment of this review noted that the authors provided insufficient information on the inclusion criteria, the review process, study design or heterogeneity between studies. In addition, only English language publications identified via MEDLINE® were included, so it is probable that some studies have been missed (CRD).

### *Evidence: Nurse-led interventions*

Summary of evidence: Nurse led interventions, with appropriate support from other healthcare providers, can result in improved outcomes for heart failure patients.

To examine the role of practice-based nurses in heart failure management interventions, Halcomb *et al* (2004) conducted a systematic review of a total of 28 studies: 12 studies based on provider surveys about the role of nurses and 16 studies based on RCTs of nurse-led interventions that took place in Australia, England, the Netherlands, Sweden, Scotland or the United States. Ten of the 16 RCTs examined provided evidence that nurse-led interventions result in decreased hospitalisations. One RCT assessed changes in quality of life and found improvements in 6 of 8 domains in the SF-36 (a multipurpose, short-form health survey). Further, 3 studies provided evidence that nurse-led interventions significantly delay mortality. However, the authors do not provide statistical information about the level of improvements observed in these studies. No independent assessment of the quality of the review was found.

This approach may be more feasible in some contexts. For example, in the UK, chronic disease management provides practice nurses with the ability to support the work of physicians by taking on some tasks typically conducted by the physician. In contrast, reimbursement policies in Australia (which primarily pay for physician services) limit the degree of services that can be delivered by nurses; nurses can generally do procedural tasks only under the supervision of a GP.

Stewart and Horowitz (2002) examined the economic and clinical effectiveness of heart failure management programmes delivered by nurse specialists by reviewing 7 studies conducted in the United States, Europe and Australia. Their review concluded that these programmes can save healthcare costs as a result of 24 to 48 per cent fewer hospital admissions overall and fewer multiple readmissions for individuals (results were statistically significant in 4 of the 7 studies reviewed). An independent assessment of the quality of this review is in progress at the CRD.

Using data from 3 key studies included in their review, the authors estimated the economic benefits of deploying a UK-wide heart failure service characterised by specialist nurse management provided via home visits to patients using data from a variety of studies, including the city-wide Glasgow Heart Failure Liaison Service in Scotland. The cost model indicated that such a service would be economically feasible if 30 per cent of hospital admissions were prevented and that the programme would be cost-saving if 50 per cent of hospital admissions were prevented. Elements of successful heart failure management programmes included the following:

- commitment to addressing the specific needs of each patient
- intervention led by a nurse specialist who provides ongoing management to provide best care with support from providers of other disciplines (that is, a multidisciplinary approach)
- at least one home visit to conduct comprehensive patient assessment
- use of appropriate medications
- increased frequency of monitoring for high-risk patients.

### ***How should care be delivered?***

#### *Background: Multidisciplinary, multifaceted care management programmes*

In the management of patients with heart failure, programme features important for success include co-ordination of care across disciplines, patient and caregiver education, patient support to improve and maintain self-management skills, effective use of post-discharge follow-up (including 24-hour access to a case manager) and appropriate use of medications (Rich, 2002). 'There is no "one size fits all" approach that represents the optimal disease management programme; rather the most effective programmes are those that are not only individually tailored to meet each patient's needs, but which are also constructed in accordance with local practice patterns, resource availability, healthcare delivery system, and method of reimbursement' (Rich, 2002, p 90). A review of such programmes found that 'compelling evidence' existed about the ability of multidisciplinary programmes to reduce readmissions without increasing costs in some populations (Rich, 2003, p22).

However, another review of heart failure management programmes implemented in a variety of countries noted the following:

- in systems with good primary care, GPs may effectively supervise and support patients with heart failure
- improvements in heart failure treatment may negate the need for heart failure management programmes
- limitations of existing studies do not provide a strong case for the adoption of heart failure programmes.

Therefore, additional research is needed to evaluate the added value of heart failure management programmes in healthcare systems with strong primary care (Bruggink-Andre de la Porte *et al*, 2005).

#### *Evidence: Multidisciplinary, multifaceted care management programmes*

Summary of evidence: There is compelling evidence that multidisciplinary, multifaceted care management programmes can effectively decrease risk of hospitalisation and mortality and improve patient quality of life. However, there is no conclusive evidence about how to organise the delivery of these programmes.

Taylor *et al* (2005) published a Cochrane Collaboration systematic review of 16 studies conducted between 1993 and 2003 to evaluate the clinical service organisation for heart failure. Studies reviewed ranged in size from 34 to 358 participants and were conducted in 9 different countries: United States (7), Sweden (2), Canada (1), Australia (1), Italy (1), Ireland (1), Scotland (1), the Netherlands (1) and New Zealand (1). Interventions were classified into the following 3 categories: multidisciplinary, case management and heart failure clinics; those focused primarily on patient education were excluded from the review. Interventions reviewed were delivered by a variety of healthcare professionals; however, nurse specialists were involved in all programmes. Data reviewed was not sufficient to issue recommendations about the optimal organisation of care for heart failure.

Specifically, evidence from a single trial of a multidisciplinary intervention reviewed suggested that heart failure-related readmission rates and hospital bed days could be reduced 43 per cent and 36 per cent respectively during the 3 months following intervention. Case management was associated with a trend towards reduced risk of all-cause mortality (varying from a 4.6 to 36 per cent decreased risk across selected studies)<sup>1</sup> and weak evidence for reduced risk of hospital admissions for heart failure. The 2 studies that involved heart failure clinics provided little support for this intervention, particularly for elderly individuals with a history of hospitalisation for heart failure. The authors called for additional research that includes multi-centre trials with larger samples of patients to ensure that studies include sufficient sample to yield statistically meaningful results.

Gonseth *et al* (2004) conducted a meta-analysis of 54 evaluations of the effectiveness of disease management programmes among elderly patients (aged 65 years or older) with heart failure conducted in Australia, Europe, South America and the United States. The authors analysed results of randomised studies and non-randomised studies separately. The randomised studies reviewed found that disease management programmes effectively reduced the risk of all-cause and heart failure-related hospitalisations. In particular, they decreased the frequency of the combined event of readmission or death by 18 per cent compared with the rate for control groups. Interventions delivered primarily in outpatient clinic visits did not yield statistically significant results. The results of non-randomised studies showed greater benefit of disease management programmes than randomised studies; however, in general, the non-randomised projects did not appropriately control for confounding factors such as disease severity.

Studies reviewed were published between 1993 and 2003 and ranged in size from 37 to 1,966 participants. The independent assessment of this review by CRD concluded that the review was conducted well and the author's conclusions are an appropriate reflection of the evidence reviewed. Specifically, publication search strategies were comprehensive and appropriate; suitable methods were employed to minimise bias and error in study selection, validity assessment and data extraction processes, and detailed evidence tables were provided.

Whellan *et al* (2005) conducted a meta-analysis of 19 studies representing 5,752 patients from 9 countries (including the United States, Canada, Australia and several European countries) to evaluate the effectiveness of heart failure disease management interventions. Sample sizes ranged from 88 to 1,966 across the studies reviewed. The authors found that follow-up conducted by a nurse practitioner or physician's assistant with follow-up conducted by a cardiologist, home nursing or telephone follow-up by a physician extender decreased the risk of hospitalisation by 50, 37 and 27 per cent respectively. Clinic care by a physician extender with supervision of a primary care provider did not affect the risk of rehospitalisation. In addition, 4 of the 10 studies that reported cost data showed significant cost savings for the

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<sup>1</sup> Based on information provided in the appendix of this review, the authors were able to calculate the percentage decrease in risk of death during study periods for six studies of case management interventions.

intervention group at the  $p < 0.05$  level; however, the authors noted that the cost data was not comprehensive, omitting, for example, pharmaceutical costs and intervention start-up costs. Because the studies included a variety of interventions, the authors concluded that the optimal organisation of care management services is not clear. Further, the multi-centre trials reviewed did not have significant impacts on heart failure outcomes, so generalising about the effects of different interventions conducted in various settings was not possible. No independent assessment of the quality of the review was found.

McAlister et al (2004) conducted a meta-analysis of 11 randomised trials of outpatient-based heart failure management programmes conducted in the United States (6 studies), Australia (2), Sweden (2) and the Netherlands (1). The studies selected for review reported either mortality or hospitalisation rates, varied in size from 97 to 1,396 participants and were published between 1993 and 1999 (McAlister et al, 2004). Interventions that included patient follow-up by a multidisciplinary team demonstrated a substantial decrease in the risk of hospitalisation. Specifically, 2 of the 9 studies that examined hospitalisation rates showed significant reductions in risk with risk ratios of 0.55 and 0.69. Further, the authors report that these 9 studies yielded a summary risk ratio of 0.77 that was statistically significant. In addition, 7 of the 9 trials that examined length of stay demonstrated that heart failure management programmes resulted in a significantly shorter length of stay or reduced total days of hospitalisation (degree of decrease was not reported). All but one of the 8 studies that examined cost savings reported that the interventions studied were cost saving (statistical significance and amount of savings were not reported). Evidence regarding the impact of programmes on mortality and quality of life was inconclusive. Programme effectiveness was not influenced by calendar year of the study, duration of the intervention or length of follow-up (range examined: one visit to 12 months).

Elements of heart failure management programmes consistent across studies included: multidisciplinary teams of health professionals, intensive patient education and self-management support, and increased access to providers, for example, specialised clinics or home visits. CRD's independent assessment of the quality of this review reported that, overall, the findings of the review appear reliable; however, the authors did not provide sufficient information about how decisions were made to include and exclude studies from the review. Further, the authors pooled results across studies of a wide range of interventions, which may not have been appropriate and limits the ability to attribute outcomes to specific interventions.

Windham *et al* (2003) conducted a systematic review of 32 studies of care management interventions, including 15 RCTs, 16 retrospective–prospective comparison studies and one descriptive study. The studies, conducted between 1971 and 2000, involved older individuals with heart failure and varied in size from 15 to 504 participants (location of interventions was not reported in the review). Similar to previous reviews, the authors concluded that care management programmes significantly reduce the risk of hospitalisation. Specifically, 16 of 28 studies that examined changes in total hospital admissions showed significant decreases in inpatient admissions as a result of care management programmes. Effects on patient quality of life, length of hospital stay and functional status are mixed: some studies show improvements in these outcomes, whereas others yield non-significant results. Five of 11 studies demonstrated significant improvements in quality of life; 6 of 8 studies showed significant improvements in functional status, and 10 of 17 studies demonstrated significant decreases in length of hospital stay. Specific information about the degree of improvement observed in each study was not provided in the review article. In addition, the authors noted that the current evidence base does not provide conclusive evidence of the cost-effectiveness of care management programmes. Based on the results of their review, the authors found the following characteristics in care management programmes that resulted in improvement in patient status or decrease in hospital stay:

- both a physician with a nurse or care manager who understand the medical and psychosocial needs of heart failure patients
- frequent patient monitoring of biological markers of ventricular function in outpatient visits, home visits, telephone calls and/or electronic monitoring (for older patients, home visits are more effective than attendance at an outpatient clinic)
- patient education about self-care activities and warning signs of an acute event, such as weight gain of several pounds over a short period
- standardised protocols for care management that are based on published, evidence-based clinical guidelines to compensate for variability in provider training, while preserving flexibility so that providers can address the specific needs of each participant.

This comprehensive literature review did not yield conclusive recommendations regarding the type of physician best suited to deliver heart failure care management services (that is, primary care versus cardiologist). CRD's independent assessment of the quality of this review suggested that results presented should be treated with caution because the authors provided insufficient information about study selection criteria and validity assessment. Since the authors reviewed only articles in English identified via MEDLINE®, it is probable that studies were missed.

Hamner (2005) conducted a systematic review of 4 types of post-hospitalisation nursing interventions for heart failure, including home-based interventions, multidisciplinary interventions, heart failure clinics and telephone or technology-based interventions. The review included 28 studies (19 RCTs and 9 non-randomised studies) that were published between 1999 and 2004. Overall, the review provided weak evidence, presented in narrative form without supporting statistics, that post-hospital nursing interventions improve patient outcomes and reduce healthcare costs. Success factors common to various types of interventions included nurses with advanced education, comprehensive patient and family education and support, involvement of healthcare providers from multiple disciplines, easy and increased access to healthcare and adequate resources for the healthcare team. Heart failure clinics and multidisciplinary interventions that include home-based components were the most effective. Multidisciplinary interventions were associated with the following outcomes: decreased risk of hospitalisation, decreased length of hospital stay, decreased mortality and improved quality of life. Neither quantitative effect sizes nor statistical significance for these effects were noted in the article. Heart failure clinics provided optimised medication management, easy access to healthcare providers and facilitated self-care through education and support from nurses. Technology-based interventions yielded limited effects on heart failure outcomes, which may be the result of challenges patients encountered with complex devices. No independent assessment of the quality of the review was found.

Bruggink-Andre de la Porte et al (2005) conducted a systematic review of heart failure management programmes, comparing results of programmes implemented in European countries with a primary care-based healthcare system with studies conducted in the United States, Canada and Australia. The 21 studies selected for inclusion in the review were published between 1995 and 2004 and ranged in size from 60 to 504 participants. Overall, 15 of the studies reviewed demonstrated improvements in one or more of the following outcomes: readmission rates, combined endpoint of readmission or death, quality of life, number of days hospitalised or decrease in healthcare costs. The authors of the review do not provide statistics describing the degree of improvements observed in each of the studies. No independent assessment of the quality of the review was found.

Despite the positive outcomes observed, the authors suggested that the evidence available is not sufficient to support widespread implementation of heart failure management programmes in a healthcare system with strong primary care resources. Disease management interventions conducted in European countries were less likely to demonstrate statistically significant improvements in outcomes than those conducted in countries with fewer primary care resources (see Table 5).

**Table 5: Outcomes of disease management interventions in European countries compared with other countries**

| Outcome                                | European countries                                 | United States, Canada, Australia, New Zealand                                 |
|--|--|---|
| Combined event of readmission or death | Significant decrease – 1 study<br>NS – 2 studies   | Significant decrease – 5 studies<br>NS – 1 study                              |
| Total rehospitalisations               | Significant decrease – 2 studies<br>NS – 4 studies | Significant decrease – 5 studies<br>NS – 5 studies<br>Significant ↑ – 1 study |
| Number of days hospitalised            | Significant decrease – 2 studies<br>NS – 3 studies | Significant decrease – 5<br>NS – 4 studies<br>Significant ↑ – 1 study         |
| Quality of life                        | Significant increase – 2 studies<br>NS – 3 studies | Significant increase – 5 studies<br>NS – 4 studies                            |

NS = not significant

Duffy and Hoskins (2004) conducted a systematic review of community-based, non-pharmacological interventions for improving heart failure outcomes published between 1998 and 2003, ranging in size from 88 to 1,966 participants (Duffy and Hoskins, 2005). Approximately 75 per cent of studies reviewed included multidisciplinary interventions and 25 per cent reported outcomes of nurse-led interventions. Based on the data available, the authors found that non-pharmacological interventions were associated with a significantly decreased risk of hospitalisation in 11 of the 14 studies that reported this outcome (the review did not include statistics to describe the degree of improvement in this measure). Two of the 4 studies reporting changes in quality of life yielded significant improvements. The authors speculated that the establishment of a trusting relationship between patients and healthcare providers, characterised by frequent communication and close monitoring of health status indicators (for example, weight), is important for effective heart failure management. Further, a nurse case manager who provides support for a patient and his or her caregiver over time helps to ensure the continuity of care and serves as a liaison among members of the healthcare team. The authors concluded that healthcare delivery models for heart failure should be redesigned to include non-pharmacological approaches to care management. The authors do not include information about the location of the 15 studies reviewed in the article. An independent review of the quality of this review is in process at the CRD.

Rich (1999) systematically reviewed 16 studies (6 RCTs and 10 observational studies) of heart failure disease management programmes and found that, overall, these programmes decreased the risk of hospitalisation, improved participant quality of life and functional



status, decreased length of stay for hospitalisations that did occur and garnered high patient satisfaction. Specifically, 9 of the 10 observational studies showed a decrease in the number of readmissions, ranging between 14 and 87 per cent fewer hospital admissions (statistical significance not noted in report), and 5 of the 6 RCTs showed similar effects with a range between 27 and 73 per cent fewer hospital admissions. Based on the limited financial data available, programmes were assessed to be cost-effective. Three of the 10 observational studies examined costs and showed savings from \$500 per patient to \$9,800 per patient. In addition, 3 RCTs reported decreases in costs; however, specific savings were reported for only one study, that is, \$460 decrease in costs per patient. The studies reviewed were published between 1983 and 1998 and ranged in size from 15 to 924 participants. The author did not note the location of studies reviewed, and no independent assessment of the quality of the review was found.

Van der Wal *et al* (2005) conducted a systematic review of 12 studies published between 1995 and 2002 that examined the effects of interventions aimed at increasing patient compliance with heart failure treatment recommendations. Most interventions included patient education delivered by different types of health professionals for different periods of time in different venues (that is, home versus clinic), rendering cross-study comparisons difficult. Seven of 9 interventions aimed at increasing compliance with medication regimens showed statistically significant improvements ranging from a 4 per cent to a 160 per cent increase in adherence. One study demonstrated a 93 per cent improvement in compliance with weighing. Two studies demonstrated significant declines in daily salt intake of 22 and 38 per cent, and 2 additional studies showed significant declines in fluid intake of 17 and 19 per cent.

The authors found support for the following strategies to increase compliance with heart failure care recommendations:

- target patients at risk (for example, patients who live alone, elderly patients, patients with multiple co-morbidities)
- implement behavioural change strategies to improve patient self-efficacy
- simplify medication regimen, if possible
- educate patients about the importance of self-care during and following hospitalisation and reinforce educational messages over time via various communication channels (for example, home visits, telephone)
- provide social support as needed.

Sample sizes of the studies reviewed varied between 20 and 200 patients. The authors did not note the location of the interventions reviewed. An independent assessment of the quality of this review is in process at CRD.

Moser (2000) reviewed 13 studies (6 RCTs and 7 non-randomised studies with pre–post design) that examined the effectiveness of specialty heart clinics, specialty care that extends to the home and increased access to primary care. In general, studies ranged in size from 15 to 190 participants; however, one study had 1,396 patients. Specialised heart failure disease management programmes have the potential to decrease heart failure-related hospitalisations and improve quality of life and patient functioning. All 4 studies reporting heart failure-related hospitalisations demonstrated significant decreases in the number of events, varying from 56 to 87 per cent. Further, 5 of 6 studies showed a significant decrease in the number of readmissions overall, ranging from 44 to 89 per cent lower (no value was reported for one study). The author was unable to identify specific elements of delivery models that improve heart failure management. The following elements of the care process were found to achieve good outcomes: frequent follow-up with patients (no specific method recommended), intensive guideline-based education about diet, medication, daily weights,

symptoms of worsening heart failure, appropriate medication regimen, methods to address early signs of fluid overload and increased access to providers. Increased access to providers in the absence of patient education was ineffective. The majority of interventions were conducted in the United States and the remainder occurred in Australia (2), Israel (1) and Sweden (1). No independent assessment of the quality of the review was found.

Coletta *et al* (2003) report the results of the Randomized Trial of Telephonic Intervention in Chronic Heart Failure (referred to as DIAL), a multi-centre randomised controlled study conducted in 51 medical centres in Argentina. The study evaluated the effectiveness of a telephone-based care management programme by comparing morbidity and mortality rates for 760 patients in the intervention group with rates for 758 individuals in the control group. The vast majority of patients in both groups were receiving guideline-concordant care, such as diuretics, ACE inhibitors and beta blockers. However, patients in the intervention group who received calls from trained nurses, at first biweekly and then monthly or as needed, were 20 per cent less likely to be admitted to the hospital for heart failure than patients in the usual care group ( $p < 0.03$ ). No effects for mortality were found.

### *Evidence: Exercise rehabilitation*

Summary of evidence: Some data suggests that rehabilitation exercise may result in improved physical functioning, which would allow heart failure patients to live independently for longer. However, there is limited data as to whether home-based or organised exercise programmes would best meet the needs of heart failure patients.

Rees *et al* (2004) conducted a comprehensive Cochrane Collaboration review of exercise rehabilitation strategies for heart failure; it supported recommendations for aerobic training for patients with stable heart failure. The review included 29 RCTs published between 1990 and 2002 that included 1,126 adults diagnosed with heart failure and excluded those who had been referred to cardiac rehabilitation previously for myocardial infarction or heart failure. Exercise training improved health-related quality of life (HRQOL) and exercise capacity in the short term. Specifically, 6 of 9 studies that measured HRQOL found that exercise training was associated with significant improvements in this outcome. Meta-analyses, which were conducted using odds ratios for dichotomous outcomes and weighted mean differences for continuous outcomes, demonstrated that exercise training results in statistically significant improvements in  $VO_2 \text{ max}^2$  (improvement of 2.16ml/kg/min), exercise duration (increase of 2.38 minutes), distance travelled on a 6-minute walk (increase of 40.9 metres) and maximum work capacity (increase of 15.1 watts).

Evidence of long-term outcomes was not available, although one study of 99 patients found that exercise training significantly reduced the risk of cardiac mortality (odds ratio = 0.32) and hospital readmissions (odds ratio = 0.28) over a 3-year follow-up period. The authors examined the effects of aerobic training in comparison with combined aerobic and resistance training and found limited research addressing the impact of resistance training. In addition, the authors found no effects related to the dose of exercise, as measured by length of exercise session, number of sessions or months of intervention. Current research does not provide evidence to support the optimal method to deliver exercise training to this population. The current literature comprises small trials of people with mild to moderate heart failure, which is not representative of the heart failure population as a whole. The studies reviewed ranged in size from 11 to 99 participants with the exception of one larger study of 181. The authors did not note the location of the studies reviewed.

<sup>2</sup>  $VO_2 \text{ max}$  is the maximum amount of oxygen in millilitres one can use in one minute per kilogram of body weight. Those who are fit have higher  $VO_2 \text{ max}$  values and can exercise more intensely than those who are not as well conditioned.

Beswick et al (2004) published an NHS Health Technology Assessment of the provision, uptake and cost of cardiac rehabilitation programmes. This systematic literature review provides the following evidence:

- Hospital discharge data for 2000 indicated that more than 9m people with heart failure in England, Wales and Northern Ireland are eligible for cardiac rehabilitation services.
- A survey of UK cardiac rehabilitation programmes provided evidence that provision of exercise services for individuals with cardiovascular disease is far from optimal. For example, only 14 to 23 per cent of myocardial infarction patients receive cardiac rehabilitation services. The numbers of heart failure patients at each clinic who were referred to, joined and completed cardiac rehabilitation were too small to allow for examination of the proportion of eligible heart failure patients in each of these categories.
- Seventeen per cent of cardiac rehabilitation services reported that they try to increase attendance of heart failure patients by employing interventions such as a specific heart failure programme or encouragement from a community-based heart failure nurse specialist.

Austin *et al* (2005) provided evidence from the UK that cardiac rehabilitation improves functional status and quality of life, reduces the risk of hospital admission and leads to fewer hospital days among individuals with heart failure. EuroQuol scores improved by 14 per cent from baseline to 24-week follow-up compared with no significant change among individuals in the control group. In addition, total scores on the Minnesota Living with Heart Failure (MLHF) questionnaire improved by 44 per cent among the intervention group compared with only 17 per cent improvement observed in the control group, although both results were statistically significant. Patients in the experimental group had 66 per cent fewer admissions and 78 per cent fewer hospital days than those in the control group during the 24-week follow-up period.

Two hundred patients under treatment at a heart failure clinic were randomised to intervention and control groups. Patients in both groups received education about symptoms of heart failure, dietary advice and a patient health record. In addition, the intervention group received a prescription for exercise, education, dietetics and, if needed, occupational therapy and psychosocial counselling. During each of the first 8 weeks, intervention patients attended 2 class sessions lasting about 2.5 hours conducted by a clinical nurse specialist. An exercise instructor supervised weekly exercise sessions for the next 16 weeks of the intervention, and patients were encouraged to exercise independently using both aerobic training and strength exercises 3 times per week.

Brodie and Inoue (2005) tested the impact of motivational interviewing (drawing on principles from client-centred counselling, cognitive behavioural therapy and social cognitive therapy) to increase physical activity among UK heart failure patients aged 65 years or older. An experienced nurse worked with patients to develop skills and social support to engage in an exercise programme during 8 sessions delivered over a 5-month period. The study randomised 60 patients to 3 groups: standard care, motivational interviewing and both interventions. Individuals in the groups that participated in motivational interviewing self-reported that they engaged in a larger variety of activities than those in the control group and exercised significantly more than the control group: 28 per cent more among those receiving standard care and motivational interviewing and 36 per cent more among those participating in motivational interviewing alone. These findings provide evidence of the effectiveness of this intervention for increasing activity among elderly individuals with heart failure.

Corvera-Tindel *et al* (2004), in a 12-week RCT of a home walking exercise programme conducted in the United States, found that the programme significantly improved functional status of patients with heart failure as measured by the 6-minute walk test and the Heart Failure Functional Status Inventory, but that it had no effect on self-reported fatigue. Persons randomised to the training group (n = 42) received the following support:

- an exercise prescription each week to walk once per day at least 5 days per week, starting with 10-minute sessions and increasing to 60-minute sessions by the end of the intervention
- a nurse-supervised walking session once per week.

Persons in the control group (n = 37) were counselled against beginning an exercise programme during the study and advised to maintain their daily routines. All 79 study participants were instructed to wear a pedometer and record the total distance walked each day. On average, intervention group members followed the exercise plan most during the first 4 weeks of the intervention; compliance decreased over time. Future studies should explore ways to maintain interest in exercise among older people with heart failure.

Jonsdottir *et al* (2006) conducted an RCT in Iceland to examine the effectiveness of a supervised exercise training programme among patients with heart failure. The intervention group (n = 21) participated in supervised exercise training 2 times per week for 5 months and attended educational sessions about nutrition, physical activity and relaxation. At the end of the study, the functional status of individuals in the intervention group improved significantly compared with the status of those in the control group, as measured by the 6-minute walk test, workload on the bicycle exercise test and time on the bicycle test ( $p < 0.05$ ). Overall self-reported quality of life did not differ significantly, but the intervention group reported higher quality of life related to exercise tolerance and general health. Although the number of patients participating in the study was low, the results were found to be statistically significant.

Haykowsky *et al* (2005) found that, among Canadian women with heart failure, a three-month regimen of supervised exercise training (aerobic training alone and a combination of aerobic training and strength training) improved exercise capacity (as indicated by oxygen volume peak measurement) and muscle strength; however, this regimen had no effect on measures of self-reported quality of life. Improvements in aerobic capacity and leg strength were not maintained following three additional months of non-supervised exercise training. Ten women were randomised to participate in exercise sessions (aerobic training supervised by a registered nurse and exercise physiologist); the other ten women received both aerobic and strength training activities under supervision. The study sample size is too small to detect differences in outcomes such as self-reported quality of life.

An observational study conducted in the Netherlands by Senden *et al* (2005) also demonstrated the effectiveness of a supervised strength and endurance training regimen among patients with congestive heart failure. The study involved 77 individuals who participated in 2 supervised and 2 non-supervised exercise sessions each week for 6 months. Exercise capacity, measured by workload and peak oxygen consumption, improved during the study period. The training regimen also preserved hamstring muscle mass.

## Telemonitoring

Summary of evidence: There is some evidence that suggests that telemonitoring may be as effective as, or more effective than, other disease management programmes for decreasing patient risk of hospitalisation and increasing quality of life. Additional research is needed to fully assess the value of telemonitoring for improving patient outcomes..

### *Background: Telemonitoring*

Another way to provide ongoing monitoring to heart failure patients is via telemonitoring, which can be an effective way to monitor heart failure patients in conjunction with other care management interventions (for example, telephone follow-up). Telemonitoring is the use of audio, video and other telecommunications and electronic information processing technologies to monitor patient status at a distance.

Telemonitoring devices include medical equipment used for monitoring vital signs (for example, scales or blood pressure cuffs) and other health measures used by patients to monitor health status. Some devices use the telephone line or other means to report results directly to healthcare providers; other items present results that patients report to providers via telephone or during in-person interactions with care management staff. Healthcare personnel can programme these devices or set up protocols to indicate changes in treatment interventions based on criteria for values that are too high or too low given patient-specific goals. Weight and blood pressure are critical early indicators of heart failure complications; therefore, telemonitoring devices have the potential to monitor patient status effectively while economising on the time of healthcare providers. However, these devices may not be appropriate for all patients; the study findings noted that approximately 20 per cent of participants in studies reviewed had difficulty using the device or were not inclined to use the device.

### *Evidence: Telemonitoring*

Louis *et al* (2003) conducted a review of 24 studies (6 RCTs, 6 observational studies and 12 non-randomised studies) of telemonitoring, that is, monitoring community-based patients using special 'telecare' devices in conjunction with telecommunication, for example, via telephone (Louis *et al*, 2003). Overall, evidence from observational studies (sample sizes ranging from 20 to 144 participants) indicated that 80 to 90 per cent of individuals were willing to use telecare devices, such as scales and blood pressure monitors. Non-randomised studies with 14 to 500 participants demonstrated that risk of hospitalisation and number of hospital days were reduced among patients routinely monitoring health status with telecare devices (percentage decrease not available from review article). However, in several cases this intervention was delivered in the context of a multifaceted multidisciplinary intervention, masking the direct relationship between telemonitoring and health outcomes.

The authors recommended that larger long-term studies be conducted to evaluate further the impact of telemonitoring on outcomes for heart failure patients because the current evidence base (largely small-scale studies) did not provide sufficient evidence of effectiveness. The location of studies reviewed was not noted in the review article. CRD is in the process of preparing an assessment of the quality of this review.

Cleland *et al* (2005) reported on the results of the Trans-European Network Home-Care Management System (TEN-HMS). This multi-site study randomised 426 patients to one of 3 treatment arms:

- Home telemonitoring (n = 168) – patients reported vital signs (that is, weight, blood pressure, heart rate and rhythm) twice a day. Nurses were alerted to out-of-range values and monitored trends of data. Patients were advised to contact the study nurse by telephone as needed. A steering group developed the protocols that defined acceptable vital sign values and indications for changes in treatment regimen.
- Nurse telephone support (n = 173) – nurses telephoned patients monthly to assess symptoms and medication regimen; patients were advised to contact the nurse by telephone as needed.
- Usual care (n = 85) – the study director sent a patient management plan to the patient's primary care physician with a request to implement the plan.

Compared with the nurse telephone group, the mean length of hospital stay was 6 days shorter for the telemonitoring group, a statistically significant finding. The risk of mortality at 12 months follow-up was significantly higher for the usual care group than for the other treatment groups. In addition, those in the usual care group had significantly more days lost to death or hospitalisation than the telemonitoring group or the group receiving nurse telephone support. More than 80 per cent of the individuals in the telemonitoring group transmitted at least one daily measurement during the 8-month intervention period.

Capomolla *et al* (2004) conducted a pilot study of home telemonitoring in the context of a multidisciplinary care management programme in Italy that also included educational sessions conducted by nurses and distribution of educational materials. Of 133 study participants, 67 were randomised to receive the intervention for approximately one year, when follow-up data was obtained; 66 individuals received usual care delivered by primary care physicians and/or cardiologists in the outpatient setting. The combined risk for rehospitalisation, emergency room visit and mortality was lower among those in the intervention group than among controls (22 versus 77 events,  $p > 0.01$ ).

Patients in the intervention group had the opportunity to contact their providers via telephone at any time to report symptoms or health problems; they were asked to submit information about their vital signs using their telephone keypads at a frequency determined by patient risk level. Specifically, high-risk patients input data every 15 days, moderate-risk patients every 30 days and low-risk patients every 60 days. Overall, compliance was 81 per cent, that is, patients transmitted their vital signs via telephone key pad in 174 of the 216 instances scheduled. Data entry errors were found in 8 per cent of interactions with the system. Data transmission occurred without error.

Benatar *et al* (2003) conducted an RCT of 216 individuals in the United States with heart failure who received care support through either telemonitoring devices and telephonic support delivered by an advanced practice nurse supported by a cardiologist or home visits conducted by a home health nurse. At the end of the 3-month intervention period, the telemonitoring group had incurred 46 per cent fewer hospital admissions for heart failure and fewer hospital days than the home visit group (13 versus 24,  $p < 0.001$ ). Further, at 6-month follow-up, the telehealth group had significantly lower costs from hospital readmissions (38 versus 63 readmissions,  $p < 0.05$ ). This trend continued at the 12-month follow-up, but differences between the groups were no longer significant. Quality of life improved significantly in both groups as measured by the Minnesotal Living with Heart Failure Questionnaire, the Quality of Life Index (Cardiac version) and the Heart Failure Self-Efficacy Scale.

Patients participating in the telemonitoring intervention tested vital signs, for example, blood pressure, heart rate, weight and oxygen saturation level, using devices that transmitted results to providers through a secure Internet site. The advanced practice nurse was notified

if values conveyed were out of acceptable ranges that the medical director and nurse had individualised for each patient.

LaFramboise *et al* (2003) conducted a pilot study in the United States of the feasibility of using a telehealth device, that is, Health Buddy<sup>®</sup> distributed by the Health Hero Network, to support patients with heart failure. Patients were randomised into 4 treatment groups: telephone nurse case management, 5 home visits for patient assessment and education by a nurse during the 2-month treatment period, care management services delivered by a telehealth device and 5 home visits and support from the Health Buddy<sup>®</sup> device. Improvements in functional status ( $p < 0.01$ ), depression ( $p < 0.06$ ) and quality of life ( $p = 0.05$ ) were similar among all study groups. In addition, most participants experienced a significant increase in self-confidence related to managing their condition; the exception was the group receiving telephone support, whose confidence decreased over the study period. These results suggest that care support provided by the Health Buddy<sup>®</sup> may be as effective as that provided by nurses via telephone or in person.

The Health Buddy<sup>®</sup> device can be programmed to conduct specific tasks as directed by a healthcare provider. For this study, the device collected information about patient health status, symptoms and health-related behaviours, and provided educational information. Protocols were based on guidelines issued by the US Agency for Healthcare Policy and Research (now the Agency for Healthcare Research and Quality).

Of the 66 patients assigned to use the device, 20 were unable to use it for a variety of reasons, such as lack of interest, poor eyesight or no electrical outlet. Some of these patients lacked a telephone service, which is clearly necessary in order to use this device. This information suggests that care management delivered by a telehealth device may require either adequate vision or a caregiver that can support the patient in the use of the device.

Artinian *et al* (2003) conducted a small RCT to test the effectiveness of a Web-based compliance monitoring device, the Med-eMonitor, to support patients with heart failure. The Web-based device was given to nine patients recruited from the heart failure clinic of the Detroit Veterans Affairs Medical Center. The device was used to assess patient symptoms, issue self-care reminders and give supportive messages for self-care on a daily basis. Each device was programmed to reflect the specific needs of each patient based on medical history and treatment plan.

From baseline to 3-month follow-up, self-reported quality of life improved significantly for the intervention group and did not change for the control group that received usual care ( $n = 9$ ). No significant differences were observed between the treatment groups related to self-care behaviours, medication compliance (determined by pill counts), functional status measured by the 6-minute walk test and NYHA functional class.

Qualitative data collected from the intervention group regarding satisfaction with the device revealed that some patients were satisfied with the device and found it helpful, whereas patients who had an established routine for taking medications found the device disruptive and troublesome. Six participants reported that the device helped them to establish a better routine for self-care activities and four reported technical difficulties using the device.

Schofield *et al* (2005) conducted an observational study of 92 elderly male patients in the US Veterans Health Administration of the effectiveness of a nurse co-ordinated care management programme that incorporated an in-home telehealth message device (Health Buddy<sup>®</sup>). The study included patients with newly diagnosed heart failure as well as those

who had been hospitalised recently for complications related to heart failure. Data was available from 73 participants at the end of the 6-month study. Patients had statistically significant improvements in several health status measures: blood pressure, weight and shortness of breath. They also had increased (more appropriate) doses of ACE inhibitor and beta blocker medications and decreased total number of hospital days, with less than one-third of hospitalisations related to heart failure.

The telehealth device allowed for daily transmission of patient data, such as weight, blood pressure, heart rate and health status to the programme nurse; it also issued patient reminders for self-care practices. The programme nurse contacted patients if a health problem was reported or vital signs were outside an accepted range. The nurse was supported by a multidisciplinary team that reviewed cases biweekly and altered patient treatment regimens as needed. The authors attributed the positive outcomes of the programme in part to the ability to view trends of patient vital signs on a routine basis, which improved appropriate dosing of heart failure medications. In addition, involvement of cardiologists increased referral rates for cardiac procedures, for example, cardiac catheterisation, that were clinically indicated and might not have been conducted for patients who did not have frequent patient monitoring or were under the care of a primary care physician.

### ***New technologies***

Summary of evidence: New innovations such as the use of a Web-based medical record that can be accessed by patients are emerging, but there is insufficient evidence to evaluate impact. Studies that test information technology solutions to increase provider adherence to evidence-based guidelines are appearing in the literature; however, there is insufficient information to assess the impact of the evidence.

#### *Background: New technologies for patients*

New innovations, such as the use of a website for electronic messaging or for enabling patients to access their medical records are emerging. We did not find any review articles that summarise evidence regarding these innovations so that the studies presented below include a mix of completed RCTs and studies that are ongoing. The evidence to date is not sufficient to assess the impact of these innovations; however, the number of these studies is likely to increase.

#### *Evidence: New technologies for patients*

Ross *et al* (2004) conducted an RCT of a Web-based medical record (SPPARO – System Providing Patients Access to Records Online) that includes clinical notes, laboratory reports and test results, and that is accessible to patients and electronic messaging between patients and providers. The website also provides an electronic version of written educational material provided to all patients who receive care from the specialty clinic involved in the study. This trial, which was conducted with patients of a heart failure specialty clinic at the University of Colorado Hospital, provides evidence of the feasibility of implementing a Web-based patient medical record and improvements in patient adherence to treatment regimens as measured after 12 months of programme participation. Members of the intervention group (n = 54) showed a trend towards greater satisfaction with patient–provider communication and no difference in self-efficacy or health status compared with the control group (n = 53) that received usual care from the heart specialty clinic. The intervention group had a significantly higher number of emergency department visits, but the



authors noted that these did not occur in conjunction with use of the online medical record. No significant differences were found for clinical service use or mortality.

Overall, participation in the trial was good; approximately 3 out of every 4 participants were still in the study at 12 months. Use of the SPPARO system was highest in the first 3 months and declined thereafter. Comparisons of patient-initiated communication with providers via telephone and/or electronic messaging (for the intervention group) showed that intervention group members used electronic messaging as a supplement rather than a substitute for telephone calls. Specifically, the intervention group made 287 calls to providers and sent 63 electronic messages; the control group made 267 calls and sent no electronic messages. The content of calls did not differ by treatment group.

Electronic medical records may not be a useful tool for all patients, as evidenced by survey data collected from 144 of 288 patients who refused to participate. 'Refusers' were similar to participants with respect to age, sex, health status and self-efficacy; however, they were more likely to have lower income and less likely to be white, have standard medical insurance, have experience with using the Internet or have a college education.

There are several ongoing studies in progress to examine the impact of providing patients with information using innovative delivery mechanisms, which will be likely to yield additional evidence about how emerging technologies can be used to support heart failure management. A randomised study of 4,000 patients at the Geisinger Clinic in Pennsylvania in the United States now in progress is examining how patient outcomes are influenced by providing information resources and tools to patients via the Internet. Data used to evaluate the intervention will be drawn from the health system's electronic health record (Stewart, 2004). Another Internet-based chronic disease self-management programme (ICDSP) is being tested at the Stanford University School of Medicine among 880 adults with heart disease, lung disease and/or Type 2 diabetes (Lorig, 2001). The Birmingham Veterans Affairs Medical Center is testing the effects of an education programme that provides customised messages to each heart failure patient based on that person's beliefs about compliance with medications, diet and self-monitoring. The intervention will be delivered in 2 modalities – paper-based and Web-based – and compared with a control group receiving usual care (Shaneyfelt, 2000).

Heisler recently began a study to examine the effectiveness of a six-month intervention combining group visits with heart failure nurse managers and a low-cost interactive voice response (IVR) telephone system that allows patients to communicate with each other and with nurse care managers through voicemail messaging. The investigator will examine the impact of care manager and peer support on patient quality of life, survival and rates of hospital admission (Heisler, 2006).

### *Background: New technologies targeted at providers*

In addition to information technology (IT) interventions targeted to patients, there are also IT interventions targeted to providers. We did not find review articles addressing IT solutions for providers so the evidence that follows includes RCTs as well as currently funded research.

### *Evidence: New technologies targeted at providers*

Subramanian *et al* (2004) conducted an RCT in the United States to evaluate the effectiveness of providing physicians with information about patient symptoms in addition to evidence-based computer-generated care guidelines compared with providing physicians with only computer-generated care guidelines. Patients treated by physicians in the intervention group (n = 355) were significantly more satisfied with their physicians

and primary care visit than those cared for by providers in the control group (n = 365). However, the authors observed no significant differences in physician implementation of care guidelines, and patient mortality at 6 and 12 months was significantly higher for the intervention group than the control group.

Feldman *et al* (2005) found that reminders of clinical recommendations specific to heart failure that were delivered to home health nurses via email significantly improved health-related quality of life of their patients. Compared with patients treated by nurses in the control group, patients of nurses receiving the intervention had better knowledge of their medications and were more likely to weigh themselves daily and refrain from adding salt to their food; however, these trends did not reach statistical significance.

Nurses randomised to the intervention group received emails with evidence-based information related to heart failure just before initiating care for a new heart failure patient. In addition, a subset of nurses in the intervention group received an augmented intervention, which included additional information for the provider in the form of an information sheet, a follow-up call from a nurse specialist, a self-care guide for patients and a prompt to support the physician–patient relationship. Interviewers blinded to intervention collected patient outcomes information 45 days after hospital discharge using the Kansas City Cardiomyopathy Questionnaire, the Geriatric Depression Scale, EuroQol EQ-5D, and investigator-developed measures of self-management and knowledge of the disease. Data reflects outcomes of 448 patients treated by nurses who did not receive treatment reminders (that is, usual care), 390 patients treated by nurses who received the basic intervention and 404 patients whose nurses received the augmented intervention.

Overall, the cost of home healthcare for patients in both intervention groups was approximately 20 per cent higher than that observed in usual care ( $p < 0.07$ ). The authors suggested that providing sufficient patient education and self-care support for patients requires more time than current routine practice of home care providers. Despite the fact that nurses' practices were most improved using the augmented intervention, patient outcomes for the usual care and intervention groups were similar. Therefore, the cost–benefit analysis indicated that the basic intervention was more cost-effective than the augmented intervention.

Baruch (2005) was recently funded by the National Heart, Lung and Blood Institute of the US National Institutes of Health to enhance and test the usability of software designed to improve provider adherence to guideline-concordant care for heart failure patients.

Bowles (2005) and others are currently conducting a study to compare the effects of delivering evidence-based disease management protocols via telephone with the effects of using telemonitoring devices for patients receiving home health services. This randomised field study includes patients with heart failure, diabetes or hypertension. At time of discharge from home healthcare, investigators will measure patient health status, self-care knowledge and behaviour, and resource utilisation.

Friedman *et al* (2002) are conducting a randomised trial to evaluate the effectiveness of a telecommunications technology for improving patient adherence to medication regimens among patients with hypertension, CHD and chronic obstructive lung disease. All patients will be invited to attend a single educational session about medication adherence, and those randomised to the active arm will participate in automated telephone conversations generated by computer on a weekly basis for six months. Although the patients in this trial

have heart disease, they do not have heart failure. Therefore, the applicability of the findings of this study to those with heart failure may be questionable. Additional research is needed to determine the effectiveness of telecommunications interventions for improving patient compliance with medication programmes.

### Where should care be delivered?

*Evidence: Heart failure clinics*

Summary of evidence: There is good evidence to support the use of heart failure clinics as part of the care delivery model for heart failure patients.

Gustafsson and Arnold (2004) conducted a systematic review of 31 studies (18 RCTs and 13 non-randomised studies) that examined the effectiveness of heart failure management programmes delivered in heart failure clinics. In general, the authors found that clinics are led by nurses, with cardiologists conducting the initial patient evaluation and development of treatment plans. The programmes significantly decreased risk of hospitalisation in 8 out of 11 non-randomised studies and 8 out of 18 RCTs. In addition, the RCTs reviewed suggest that programmes with home visits are more effective than those without home visits: 5 out of 8 studies including home visits resulted in a significant decrease in risk of readmission. The authors concluded that heart failure clinics should be part of the healthcare delivery model for this disorder and recommended that the care delivered at these sites be monitored routinely to ensure that quality remains high. To foster comparisons between clinics, a common electronic database should be used to monitor care. Heart failure clinics should be set up to meet local needs, because existing literature does not provide sufficient evidence to identify the optimal design of such clinics and services. No independent assessment of the quality of the review was found.

**Table 6: Summary of recent and ongoing delivery system studies for the care of patients with heart failure funded by the Centers for Medicare and Medicaid Services in the United States**

|  |                 |                    |
|--|-----------------|--------------------|
| <p><b>Current population-based studies of chronic care delivery in the United States</b><br/>                 There are a number of ongoing studies to examine methods for delivering chronic care support for the management of heart failure in the United States under the sponsorship of the US Centers for Medicare and Medicaid Services. These large, population-based studies will address some of the weaknesses identified in earlier disease management studies. However, these studies are being conducted within the context of the United States healthcare system so the extent to which findings will be generalisable to the UK will need to be considered.</p> |                 |                    |
| <b>Name of demonstration</b>   | <b>Duration</b> | <b>Description</b> |

Table continues on next page...

|  |   |  |
|--|---|--|
| Medicare Disease Management Demonstration                            | Began 1 January, 2004; operations ended 31 December, 2005. Results of the demonstration are forthcoming (Centers for Medicare and Medicaid Services, 2003). | The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 mandated a randomised study of up to 30,000 Medicare fee-for-service (MFFS) beneficiaries participating in one of 3 disease management programmes operating in California, Arizona, Louisiana and Texas. Beneficiaries with congestive heart failure, diabetes or coronary heart disease living in the demonstration service areas received disease management services and pharmaceutical benefits.                                 |
| Voluntary Chronic Care Improvement under Traditional Fee-For-Service | Programmes launched between August, 2005 and January, 2006; they will run for three years.  | Each of 8 pilot programmes in as many states involves 20,000 beneficiaries randomised to the intervention group and 10,000 beneficiaries randomised to the control group. Programmes are run by third-party companies, employ an intent-to-treat model and are performance based. Results of the programme, referred to as Medicare Health Support, will be released in 2 reports to the US Congress in August 2007 and February 2009 (Foote, 2004).   |
| The Care Management for High-Cost Beneficiaries Demonstration        | Programmes launched between October, 2005 and August, 2006; they will run for three years.  | This demonstration is unique in that it focuses exclusively on beneficiaries who are judged to be 'high cost' based on their historical Medicare costs or at high risk for future healthcare use based on claims-based measures of disease severity. Evaluation of the programme will include assessment of beneficiary and provider satisfaction and examination of the specific programme features that were most helpful to subgroups of the populations served (Centers for Medicare and Medicaid Services, 2005). |

## Acute care

Heart failure can entail frequent hospital admissions; one goal of care management of this chronic illness is to manage symptoms and thereby avoid hospitalisations. Delivery of guideline-concordant inpatient treatment during a sentinel event such as a hospitalisation, coupled with the initiation of interventions before and at discharge to enable better self-management in the community, can decrease the frequency of subsequent readmissions; this in turn lowers the cost of care, improves clinical outcomes and raises the patient's quality of life.

Patients experiencing acute exacerbations of heart failure seek care in acute care settings such as hospitals and emergency rooms; the requirements typically are to relieve fluid retention and restore the heart's ability to pump blood effectively. A hospitalisation can offer an opportunity to begin the process of patient education and self-management support regarding behaviours and lifestyle issues (for example, diet and exercise) that prevent or

delay future exacerbations of heart failure. The time of discharge can be a critical window of opportunity because recently hospitalised patients may be particularly amenable to care recommendations to avoid future admissions.

### Guidelines for acute care of heart failure

Although guidelines are available to inform treatment options for heart failure, few present 'best practices' for delivery models for acute care services (Swedberg *et al*, 2005). However, performance measures related to heart failure have been developed, such as those issued by the Joint Commission for the Accreditation of Hospitals (JCAHO) in the United States:

- provide patients with appropriate discharge instructions
- conduct assessment of left ventricular systolic function (LVEF)
- prescribe ACE inhibitors to patients with heart failure and an ejection fraction of 40 per cent or less, in the absence of contraindications
- provide smoking cessation counselling to current smokers.

Fonarow (2005) reports on compliance with these JCAHO standards using data from approximately 62,000 patients in the Acute Decompensated Heart Failure National Registry (ADHERE). Initiated in October 2001, ADHERE is a national registry of patients hospitalised for acute decompensated heart failure. More than 275 hospitals have submitted encrypted data from patient medical records to this repository, which is used to understand the characteristics and management of heart failure and, ultimately, improve care for people with heart failure (Anonymous, 2005). Compliance was highest for assessment of LVEF (85 per cent) and receipt of ACE inhibitors (72 per cent). In contrast, only 51 per cent of smokers received counselling about smoking cessation and only 36 per cent of patients received education about diet, weight monitoring, activity level, worsening symptoms, follow-up appointments and medication management at discharge.

### Evidence summary: Inpatient care for heart failure

From the evidence presented below, we conclude that post-discharge mortality is not influenced by whether a patient was treated by a primary care physician (for example, GP) or specialist. Initiating transitional care from hospital to community by an advanced practice nurse has the potential to reduce hospital length of stay and risk for readmission. Starting care management strategies during the inpatient stay appears to reduce the risk of readmission. Overall, type of hospital has not been demonstrated to affect quality of care and patient outcomes. The findings suggest that elements of the process of care conducive to good outcomes are the critical factors; these can be provided by a variety of personnel in a variety of settings.

### *Where should be delivering care?*

*Evidence: Care provided by cardiologists and GPs*

SumSummary of evidence: There is insufficient evidence to assess whether inpatient care for heart failure should be delivered by a generalist or specialist.

Heart failure patients are typically cared for by GPs, internists or family practice physicians, rather than specialists (Tu *et al*, 2004). Auerbach *et al* (2000) conducted a multi-site prospective cohort study in the United States to examine the quality of care, costs and outcomes of patients hospitalised with heart failure whose attending physician was a cardiologist rather than a non-specialist. Multivariate analyses adjusting for patient

characteristics and disease severity showed that patients cared for by cardiologists were significantly more likely to receive more intensive treatment, such as right-heart catheterisation (odds ratio [OR] = 2.9), cardiac catheterisation (OR = 3.9) or transfer to an intensive care unit (OR = 2.8). Consequently, the healthcare costs for patients treated by a cardiologist were 43 per cent higher than those treated by a GP. Despite the higher intensity of care provided, 30-day mortality rates did not differ significantly between the 2 groups; however, a non-significant trend towards improved survival at one year was observed for those treated by a specialist.

*Evidence: Transitional care provided by an advanced practice nurse*

Summary of evidence: Transitional care that spans inpatient and outpatient services, delivered by an advanced practice nurse, can reduce hospital length of stay and risk of readmission.

Brooten *et al* (2002) reviewed 7 RCTs of a discharge planning intervention conducted in the United States and delivered by an advanced practice nurse with a physician available to address complex issues; the patients were 276 elderly persons with cardiac medical and surgical diagnoses. An advanced practice nurse is a nurse who typically has 2 additional years of education beyond a baccalaureate degree, can diagnose and treat illnesses and provide healthcare, and often can prescribe medications. A transitional care model using advanced practice nurses was originally developed to promote early discharge of high-risk patients from the hospital by substituting transitional care for a portion of inpatient care. It includes comprehensive discharge planning, patient assessment, education, counselling, support and post-discharge support (that is, home visits and access to the nurse via telephone). This approach improved the risk of hospital admission and the length of hospitalisation (statistics describing the degree of improvements were not provided in the article). The key success factors for advanced practice nurses include the following:

- advanced understanding of disease process to establish credibility among patients and other health professionals
- knowledge of community resources and ability to negotiate for these resources
- skills in teaching, counselling and patient advocacy.

Brooten *et al* (2003) published another review of advanced practice nurse interventions in the United States to examine the impact of comprehensive discharge planning among 5 different populations, including one study of elders with cardiac medical and surgical diagnoses. These intervention studies are distinct in that the advanced practice nurse determines the timing and frequency of interactions with patients, in contrast to home care, which occurs on a schedule determined by payment regulations. Similar to the earlier review, this article provided evidence that this type of transitional care reduces the risk of hospitalisation, reduces length of stay and saves money (statistics describing the degree of improvements were not provided in the article). Because patient interactions last only 22 minutes, on average, these nurses are most successful if they are skilled at conducting patient assessment, providing targeted and effective patient education and negotiating for resources within the health system.

## When should care management services be initiated?

*Background: Initiating chronic care support during the hospital stay*

To reduce the risk of 90 day readmission and improve patient outcomes the following clinical interventions need to be initiated during the hospital stay: patient education; the involvement of heart failure specialists in the determination of which medications to prescribe; and the

use of specific criteria to assess patient readiness for discharge (McDonald and Ledwidge, 2003). Adding care management services to the inpatient stay has been found to lengthen hospital stays in countries such as the United States, where the average length of stay for a heart failure admission is 5 days. In contrast, implementing care management support in European or Australian markets, where the average length of stay is 11 to 16 days, may increase efficiency and decrease length of stay for these admissions. Further, the addition of a service line for heart failure in an acute care setting permits a defined set of individuals (cardiologists or physicians with an interest in heart failure supported by a heart failure nurse specialist) to take responsibility for delivering guideline-concordant care to all patients admitted with this diagnosis.

*Evidence: Initiating chronic care support during the hospital stay*

Summary of evidence: Starting care management strategies during the inpatient hospital stay lowers the risk of hospital readmission.

Phillips *et al* (2004) conducted a meta-analysis of 18 RCTs from 8 different countries, including Holland, Australia, Sweden, Ireland, England, Canada, Italy and the United States. Overall, the review included 3,304 older patients with congestive heart failure randomised into interventions with comprehensive discharge planning conducted during the index admission and post-discharge support or control groups receiving usual care. Over an average of 8 months following hospitalisation, individuals receiving care management support were 25 per cent less likely to be rehospitalised ( $p < 0.05$ ) than those in control groups. In addition, a greater proportion of intervention group members (26 per cent) compared with control group members (14 per cent) had improved quality of life scores compared with their respective baseline scores ( $p < 0.05$ ); the authors observed a non-significant trend towards decreased risk of mortality. Among studies conducted outside the United States, healthcare costs for intervention patients were not significantly different from those of control patients; however, intervention groups had significantly lower costs in studies conducted in the United States. Specifically, intervention patient costs were on average \$536 lower than control patient costs. The authors concluded that the evidence supports routine application of comprehensive discharge planning and post-discharge support for older hospitalised patients with heart failure to support the transition from acute hospital care to home. A CRD assessment of the quality of this study notes that this was a full review with clearly defined aims; however, the available evidence was difficult to interpret given the variety of interventions in the studies included in the review. Some studies may have been missed due to the fact that only English language publications were included.

Balinsky and Muennig (2003) examined care management interventions that begin in the inpatient setting; in these programmes, patient interactions with healthcare providers are more intensive than those conducted on an outpatient basis and interventions can be delivered consistently in a controlled setting. In particular, they reviewed studies of programmes that used at least three of the following six components:

- care co-ordination by a multidisciplinary team
- medication review and/or planning
- hospital-based education programme
- comprehensive discharge planning
- post-discharge patient education via home visits or outpatient clinic visits
- home care by a licensed clinician.

The 4 RCTs reviewed, which involved patients aged 65 years or older, were conducted in the United States and provided evidence that care management services for heart failure initiated in the inpatient setting decrease risk of hospital readmission (from 42 to 62 per cent) and lower healthcare costs (from \$2,251 to \$19,700 per patient per year). Based on the review, the authors found the following to be important issues when setting up an inpatient management programme: hospital culture, such as physician interest in participating in a multidisciplinary team, needs of the local population and financial capacity and infrastructure needs of the hospital. A CRD assessment of the quality of this review notes that there was insufficient information about study selection, data extraction and validity assessment techniques employed; however, the authors' conclusions were appropriately conservative.

Evidence from more than 60,000 cases documented in the ADHERE registry (2005) suggested that heart failure patients who begin their treatment in the emergency department receive critical therapies sooner than those who are admitted to an inpatient unit on arrival to the hospital. Diuretic and intravenous vasoactive therapies were initiated within 2.1 hours of presentation at the emergency department; these same therapies were not initiated until more than 16 hours and 35 hours respectively after direct admission to an inpatient unit. The authors suggested that earlier initiation of therapy may result in fewer hospital days (Fonarow, 2005).

## Where should acute care for heart failure be delivered?

*Evidence: Type of facility for delivery of acute care for heart failure*

Summary of evidence: The type of hospital, or type of unit within a hospital, to which patients are admitted may not affect quality of care and patient outcomes, but the evidence is weak and not definitive.

Di Lenarda et al (2002) reported results from the Heart Failure Epidemiological Study in Italian People (TEMISTOCLE), an observational study that examined the effect of hospital department on service utilisation, patient management and outcomes; the results were based on 789 patients in 167 cardiology departments and 1,338 patients treated in 250 internal medicine departments in Italy (Di Lenarda et al, 2002). Patients treated in cardiology departments were younger, more likely to be male and more likely to present with higher disease severity than patients treated in internal medicine units. Patients treated in cardiology departments were significantly more likely to undergo coronary angiography (7.5 versus 0.9 per cent), have an assessment of LVEF (89.3 versus 54.8 per cent) and receive beta blocker medications. Prescription of ACE inhibitors and patient outcomes (that is, in-hospital mortality, 6-month readmission and post-discharge mortality rates) were similar between the 2 types of units.

Butler et al (2003) conducted an observational study to examine care provided at 24 hospitals in Tennessee in the United States to determine whether hospital size (as indicated by number of beds), geographic location and teaching affiliation were related to the following quality of care measures: appropriate use of ACE inhibitors, documentation of ejection fraction and patient education about appropriate self-care activities. Chart abstraction data from 1,180 Medicare patients with heart failure showed that hospital type was not related to use of ACE inhibitors; however, urban and teaching hospitals were significantly more likely to document ejection fraction than other hospitals (17 and 20 per cent more respectively). Further, hospitals with 100 beds or more were at least 55 per cent more likely to document ejection fraction than smaller hospitals ( $p < 0.05$ ). The relationship between hospital type and provision of patient education to support self-care varied by type of educational



intervention (exercise counselling, sodium counselling, outpatient follow-up and telephone contact). No particular type of hospital performed best across all measures. The authors noted that there was room for improvement in quality of care across all hospital types.

Heart failure observation units (OUs) serve as an alternative to a hospital's emergency department, inpatient unit or critical care unit for treating patients with stable vital signs and no significant complications. OUs that operate with established protocols for diagnosing, monitoring, treating and educating patients have the potential to improve patient outcomes and decrease the risk of hospital admissions, therefore potentially decreasing costs of care (Peacock et al, 2006). Two related studies suggest that protocols for OU care include the appropriate use of diuretics, ACE inhibitors and vasoactive agents, patient education and tracking provided in an outpatient unit (Peacock and Emerman, 2004; Peacock et al, 2006). Further, patients who were admitted to the hospital from the heart failure OU spent fewer total days in hospital, on average, than those who were admitted directly to the inpatient unit. Patients who can benefit from care in a heart failure OU and have a low risk of adverse outcomes are those who meet the following criteria:

- initial systolic blood pressure > 160mm Hg
- no ischaemic changes on ECG
- negative cardiac markers of ischaemia (Peacock and Emerman, 2004).

## III. Conclusions

### Limitations of the literature and evidence base

Overall, the quality of the literature reviewed was variable and the generalisability of the available evidence base was greatly limited for several reasons. Further, the comparability of studies conducted is limited because of the variety of measures used to operationalise a single construct, such as health status, and varying time horizons of each intervention and follow-up periods. We discuss below issues related to the quality of studies conducted, the ability to compare results across studies and generalisability.

With respect to the quality of individual studies, three considerations come into play. The first is that we did not grade the quality of review articles according to the CONSORT statement or other standards. The quality of these publications, however, is variable. Second, we made no attempt to evaluate the quality of constituent studies in these review articles (as that would have entailed reviewing them separately, which would have made using the review articles irrelevant). Third, we did no formal evaluation of the RCTs included in this report. Thus, we can comment only in general terms about the problems observed or noted explicitly in the literature we reviewed.

The first main point is that the authors of many studies noted that a causal link between the interventions and health outcomes of interest could not be demonstrated (Philbin, 1999; Rich, 1999; Rich, 2002; Rich, 2003; Moser, 2000; McAlister *et al*, 2001; Windham *et al*, 2003; Duffy *et al*, 2005; Gustafsson and Arnold, 2004; van der Wal *et al*, 2005). Trials done to date may have been too short to show effects of chronic care interventions on mortality or long-term costs (Balinsky and Muennig, 2003; McAlister *et al*, 2001).

Second, several authors noted that interventions were not described sufficiently (McAlister *et al*, 2001; Windham *et al*, 2003; Balinsky and Muennig, 2003; Gonseth *et al*, 2004; Phillips *et al*, 2004; Ara, 2004; Duffy *et al*, 2005; Bruggink-Andre de la Porte *et al*, 2005). Similarly, many studies lacked adequate information about the 'usual' or 'standard' care provided to control or comparison groups (Gonseth *et al*, 2004; Phillips *et al*, 2004; Hamner, 2005). Descriptions or operational definitions of clinical outcomes or of the psychometric properties of instruments used to measure outcomes were often inadequate (Duffy *et al*, 2005). Gwadry-Sridhar *et al* (2004), for instance, noted that measures of quality of life varied across studies, so comparing the results of interventions even on this outcome is complicated. Many of these studies were multifaceted, and investigators were able only to report on the impact of entire programmes or models, not the elements that might have been more (or less) important to the outcomes measured. Gustafsson and Arnold (2004), for example, noted that the relative contributions of doctors and nurses were difficult to sort out in the studies reviewed about heart failure clinics and outpatient management of heart failure (also see Arnold *et al*, 2006).

Third, other concerns include lack of information about patient selection criteria (Windham *et al*, 2003) and lack of information about patient comprehension and patient attrition or levels of dropout of interventions (Philbin, 1999).

Authors of several review studies noted the challenges of comparing results across studies (van der Wal *et al*, 2005; Bruggink-Andre de la Porte *et al*, 2005; Hamner, 2005; Gwadry-Sridhar *et al*, 2004) quite apart from the challenges of applying meta-analytic techniques appropriately within a given review article. Specifically, studies included different populations, assessed different outcomes with different measures and employed different

interventions over different time periods. These factors seriously hindered our ability to amass evidence that supports the use of one intervention model over another.

Poor generalisability stemmed from several problems. One was the small sample sizes of many studies reviewed (Philbin, 1999; Rich, 1999; Rich, 2003; Moser, 2000; McAlister *et al*, 2001; Balinsky and Muennig, 2003; Gonseth *et al*, 2004; Gustafsson and Arnold, 2004; Gwadry-Sridhar *et al*, 2004; Ara, 2004; Bruggink-Andre de la Porte *et al*, 2005; Hamner, 2005; Taylor *et al*, 2005). However, this is less of a problem for the meta-analyses included in this review. Some RCTs included in review articles had as few as 15 participants; however, several observational studies included large samples. Further, many studies, especially the trials, employed rigorous inclusion criteria, such as those that excluded individuals with severe co-morbid conditions or residents of nursing homes (Rich, 1999; Moser, 2000; Taylor *et al*, 2005). Available evidence relies largely on studies that did not record race or ethnicity (Moser, 2000; Hamner, 2005). Finally, many studies were conducted at academic medical centres, or in the United States, which may not be representative of the resources available in most communities and may not reflect practice patterns or resources available in the UK (Rich, 1999; Moser, 2000; Balinsky and Muennig, 2003; Duffy *et al*, 2005). In short, the evidence we found is not likely to be completely representative of the entire range of patients with heart failure. However, many of the studies focused on elderly patients with heart failure, which makes up a large proportion of those afflicted.

## Findings

In this review we focused primarily on three areas related to the organisation and delivery of healthcare for patients with heart failure:

- adequate diagnosis so that appropriate treatment can be initiated
- chronic care management
- inpatient treatment for acute exacerbations.

The evidence is summarised in Table 7.

**Table 7: Summary of evidence – healthcare delivery models for heart failure**

| Area of focus   | Summary of evidence  |
|---|--|
| Adequate diagnosis so that appropriate treatment can be initiated | <ul style="list-style-type: none"> <li>• Evidence of the effectiveness of open access to echocardiography is limited.</li> <li>• Evidence supports the use of an algorithm for heart failure investigation that uses less expensive tests, such as electrocardiogram and/or blood tests of natriuretic peptides, as a means of triaging patients who need an echocardiogram.</li> </ul>  |
| Chronic care management   | <ul style="list-style-type: none"> <li>• The extant evidence on the effectiveness of disease management in heart failure programmes is mixed.</li> <li>• The evidence supports multidisciplinary management and multifaceted interventions; however, there is no conclusive evidence about how to organise the delivery of these programmes.</li> <li>• There is some evidence to suggest that, compared with GPs, cardiologists provide care that is more consistent with guidelines and have better patient outcomes. This is particularly the case for the likelihood of patients receiving ACE inhibitors and beta blockers.</li> <li>• Chronic care management activities can be effectively delivered by nurses with advanced training, with support and back-up from physicians.</li> <li>• The evidence supports the delivery of chronic care interventions in multiple ways including specialty clinics, home-based interventions and disease management programmes; no one model emerged as superior.</li> <li>• The evidence suggests that chronic care management can be provided in a GP's office with the support of a nurse specially trained to monitor these patients.</li> <li>• There is some evidence that suggests that telemonitoring may be as effective as, or more effective than other disease management programmes for decreasing patient risk of hospitalisation and increasing quality of life. Additional research is needed to fully assess the value of telemonitoring for improving patient outcomes.</li> </ul> |
| Inpatient treatment for acute exacerbations                       | <ul style="list-style-type: none"> <li>• Evidence supports transitional care, begun during the hospital stay and continuing into the community, delivered by an advanced practice nurse; it can reduce hospital length of stay and risk of readmission.</li> <li>• The evidence supports starting care management strategies during the inpatient hospital stay to lower the risk of hospital readmission.</li> </ul>  |

The debate in the literature regarding diagnosis is whether open access to echocardiography is effective. Our findings revealed that the evidence of the effectiveness of open access to echocardiography is limited: we found no RCTs examining the impact of this healthcare delivery option. We did find that the use of an algorithm for heart failure investigation that uses less expensive tests, such as electrocardiogram and/or blood tests of natriuretic peptides as a means of triaging patients who need an echocardiogram, may be a cost-effective strategy for diagnosing patients suspected of having heart failure.

Chronic care management for heart failure is best provided by a multidisciplinary team providing multifaceted interventions. The elderly represent a substantial proportion of heart failure patients. These patients are often complex and present with both medical symptoms and cognitive deficits. Elderly heart failure patients present with an increased prevalence of concomitant disease; thus, those who are being treated for heart failure are also likely to be receiving treatments for other conditions and therefore face a higher risk of drug interactions and non-compliance (Swedberg *et al*, 2005). The evidence supports multidisciplinary management and multifaceted interventions as effective approaches to improve pharmacologic treatment as well as to address the multiple needs presented by these patients.

There is some evidence to suggest that, compared with GPs, cardiologists provide care that is more consistent with guidelines and have better patient outcomes. This is particularly the case for the likelihood of patients receiving ACE inhibitors and beta blockers. However, the evidence is limited and findings are mixed. Chronic care management activities can be effectively delivered by nurses with advanced training, with support and back-up from physicians. Ideally, all providers, regardless of specialty, who are treating patients with heart failure, should have experience and particular expertise in managing this specific condition.

While there is compelling evidence that multidisciplinary, multifaceted care management programmes can effectively decrease risk of hospitalisation and mortality and improve patient quality of life, there is no conclusive evidence about how to organise the delivery of these programmes.

The increasing prevalence and high cost of treating heart failure patients have motivated payers and health policy-makers to seek new methods of managing care for these patients. In the past decade, disease management programmes, have been reported to reduce the cost of caring for chronically ill patients (Harrison *et al*, 2002). The Disease Management Association of America defines disease management programs as a 'system of co-ordinated healthcare interventions and communications for populations in which patient self-care efforts are significant' (Disease Management Association of America, 2007). Disease management is growing in popularity with the majority of managed care organisations in the United States which implement at least one disease management programme. Germany is developing national policy for widespread disease management programmes. However, the extant evidence on the effectiveness of disease management in heart failure programmes is mixed (Smith *et al*, 2005). The evidence supports the delivery of chronic care interventions in multiple ways including specialty clinics, home-based interventions and disease management programmes; no one model emerged as superior. The evidence suggests that chronic care management can be provided in a GP's office with the support of a nurse specially trained to monitor these patients.

There is some evidence that suggests that telemonitoring may be as effective as, or more effective than, other disease management programmes for decreasing patient risk of hospitalisation and increasing quality of life. Telemonitoring involves an increased dose of diuretics. Additional research is needed to fully assess the value of telemonitoring for improving patient outcomes. In addition, studies that test IT solutions to increase provider adherence to evidence-based guidelines are appearing in the literature; however, there is insufficient evidence to assess the impact of the evidence.

While there is evidence to support the benefit of an exercise programme for patients with heart failure, there is insufficient evidence to recommend a specific delivery modality for supporting people with heart failure in their efforts to exercise. Supervised exercise training, a home walking programme and motivational interviewing may be effective at improving functional status, exercise capacity and quality of life. According to Austin *et al*

(2005), cardiac rehabilitation is widely available in the UK. Cardiac rehabilitation has been demonstrated to be effective for cardiovascular disease such as post-myocardial infarction but has not been tested as much for heart failure. There is limited data regarding the best way to provide this service to heart failure patients.

One of the goals of chronic management of heart failure is to manage the patient in such a way that hospitalisations are avoided. However, acute exacerbations necessitating inpatient stays do occur with regularity in this population of patients. Transitional care delivered by an advanced practice nurse, begun during the hospital stay and continuing into the community, can reduce hospital length of stay and risk for readmission. The evidence supports starting care management strategies during the inpatient hospital stay to lower the risk of hospital readmission.

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## Appendix: Search strategies

**Table A-1. Search strategy for review articles about healthcare delivery models for heart failure**

| Search Strategy   | MEDLINE® Results |
|---|------------------|
| <b>Limits:</b>  |                  |
| <ul style="list-style-type: none"> <li>• All Adult: 19+ years,</li> <li>• English,</li> <li>• Publication Date from 1995,</li> <li>• Review (for MEDLINE®),</li> <li>• Humans</li> </ul>  |                  |
| <b>Step 1 – Search health systems terms</b>   | 11,229           |
| <ul style="list-style-type: none"> <li>• ‘Disease Management’[MeSH] OR</li> <li>• ‘National Health Programmes’[MeSH] OR</li> <li>• ‘Community Health Planning’[MeSH] OR</li> <li>• ‘Community Health Services’[MeSH] OR</li> <li>• ‘Community Networks’[MeSH] OR</li> <li>• ‘Delivery of Healthcare’[MeSH] OR</li> <li>• ‘center of excellence’ [tw] OR</li> <li>• ‘regionalisation’ [tw] OR</li> <li>• ‘regionalization’ [tw] OR</li> <li>• ‘referral management’ [tw] OR</li> <li>• ‘Triage’[MeSH] OR</li> <li>• ‘Case Management’[MeSH] OR</li> <li>• ‘Organisational Case Studies’[MeSH] OR</li> <li>• ‘Risk Management’[MeSH] OR</li> <li>• ‘service lines’ [tw] OR</li> <li>• ‘Programme Evaluation’[MeSH] OR</li> <li>• ‘Regional Health Planning’[MeSH] OR</li> <li>• ‘Emergency Treatment’[MeSH] OR</li> <li>• ‘Emergency Medical Services’[MeSH] OR</li> <li>• ‘Emergency Service, Hospital’[MeSH] OR</li> <li>• ‘Emergency Medicine’[MeSH] OR</li> <li>• ‘timeliness’ [tw] OR</li> <li>• ‘Rehabilitation’[MeSH]</li> </ul> |                  |
| <b>Step 2 – Search heart failure</b>  | 1,039            |
| <ul style="list-style-type: none"> <li>• ‘Heart Failure, Congestive’[MeSH] OR</li> <li>• ‘chronic heart failure’ [tw] OR</li> <li>• ‘heart failure’ [tw]</li> </ul>   |                  |
| <b>Step 3 – Search Quality terms</b>  | 34,482           |
| <ul style="list-style-type: none"> <li>• ‘Quality Assurance, Healthcare’[MeSH] OR</li> <li>• ‘Quality Indicators, Healthcare’[MeSH] OR</li> <li>• ‘Quality-Adjusted Life Years’[MeSH] OR</li> <li>• ‘Quality of Healthcare’[MeSH] OR</li> <li>• ‘Healthcare Quality, Access, and Evaluation’[MeSH] OR</li> <li>• ‘Quality of Life’[MeSH] OR</li> <li>• ‘Cost of Illness’[MeSH] OR</li> <li>• ‘appropriate*’ [tw] OR</li> </ul>  |                  |

|  |            |
|--|------------|
| <b>Step 3 – Search Quality terms continued</b>   |            |
| <ul style="list-style-type: none"> <li>• ‘Safety Management’[MeSH] OR</li> <li>• ‘patient safety’ [tw] OR</li> <li>• ‘Process Assessment (Healthcare)’[MeSH] OR</li> <li>• ‘performance measures’ [tw] OR</li> <li>• ‘Cost-Benefit Analysis’[MeSH] OR</li> <li>• ‘Patient Compliance’[MeSH] OR</li> <li>• ‘Guideline Adherence’[MeSH]) OR</li> <li>• ‘Continuity of Patient Care’[MeSH] OR</li> <li>• ‘Efficiency’[MeSH] OR</li> <li>• ‘Efficiency, Organisational’[MeSH]) OR</li> <li>• ‘Patient Compliance’[MeSH] OR</li> <li>• ‘Information Systems’[MeSH] OR</li> <li>• ‘Hospital Information Systems’[MeSH] OR</li> <li>• ‘Management Information Systems’[MeSH] OR</li> <li>• ‘Clinical Pharmacy Information Systems’[MeSH] OR</li> <li>• ‘Ambulatory Care Information Systems’[MeSH] OR</li> <li>• ‘Telemedicine’[MeSH] OR</li> <li>• ‘care pathway’ [tw] OR</li> <li>• ‘care protocol’ [tw] OR</li> <li>• ‘practice guideline’ [tw]</li> </ul> |            |
| <b>Step 4 – Search Outcomes terms</b>  | 31,090     |
| <ul style="list-style-type: none"> <li>• ‘Health Status’[MeSH] OR</li> <li>• ‘Outcome Assessment (Healthcare)’[MeSH] OR</li> <li>• ‘Mortality’[MeSH] OR ‘Hospital Mortality’[MeSH] OR</li> <li>• ‘ambulatory care sensitive conditions’ [tw] OR</li> <li>• ‘Morbidity’[MeSH] OR</li> <li>• ‘complications’[Subheading] OR</li> <li>• ‘Sentinel Surveillance’[MeSH] OR</li> <li>• ‘Fatal Outcome’[MeSH] OR</li> <li>• ‘Self Care’[MeSH] OR</li> <li>• ‘Activities of Daily Living’[MeSH] OR</li> <li>• ‘outcome’ [tw]</li> </ul>  |            |
| <b>Step 5 – Intersection of heart failure, health system, quality, and outcomes terms</b>  | 101        |
| Step 1 AND Step 2 AND Step 3 AND Step 4  |            |
| <b>Step 6 –Intersection of heart failure, health system, and quality terms that were not included with the intersection of outcomes terms</b>  | 0          |
| Step 1 AND Step 2 AND Step 3 AND NOT Step 5  |            |
| <b>Step 7 – Intersection of heart failure, health system, and outcomes terms that were not included with the intersection of quality terms</b>   | 8          |
| Step 2 AND Step 3 AND Step 4 AND NOT Step 5  |            |
| Step 8 – Searched ‘Related Articles’ for 5 relevant articles   | 165        |
| <b>Total review articles</b>   | <b>274</b> |



**Table A-2. Search strategy for randomised controlled trials of healthcare delivery models for heart failure**

| Search strategy   | MEDLINE®<br>Results | CINAHL<br>Results |
|---|---------------------|-------------------|
| <b>Limits:</b>  |                     |                   |
| <ul style="list-style-type: none"> <li>• All Adult: 19+ years,</li> <li>• English,</li> <li>• Publication Date from 2003,</li> <li>• Randomised Controlled Trial (MEDLINE®),</li> <li>• Humans</li> </ul>   |                     |                   |
| <b>Step 1- Search Heart Failure</b>   |                     |                   |
| <ul style="list-style-type: none"> <li>• 'Heart Failure, Congestive'[MeSH] OR</li> <li>• 'chronic heart failure' [tw] OR</li> <li>• 'heart failure' [tw]</li> </ul>   | 695                 | 3,094             |
| <b>Step 2 – Search health systems terms</b>   |                     |                   |
| <ul style="list-style-type: none"> <li>• 'Disease Management'[MeSH] OR</li> <li>• 'National Health Programs'[MeSH] OR</li> <li>• 'Community Health Planning'[MeSH] OR</li> <li>• 'Community Health Services'[MeSH] OR</li> <li>• 'Community Networks'[MeSH] OR</li> <li>• 'Delivery of Healthcare'[MeSH]) OR</li> <li>• 'center of excellence' [tw] OR 'centre of excellence' [tw] OR</li> <li>• 'centers of excellence' [tw] OR</li> <li>• 'centres of excellence' [tw] OR</li> <li>• 'regionalisation' [tw] OR</li> <li>• 'regionalization' OR</li> <li>• 'referral management' [tw] OR</li> <li>• 'Triage'[MeSH] OR</li> <li>• 'Case Management'[MeSH] OR</li> <li>• 'Organisational Case Studies'[MeSH]) OR</li> <li>• 'Risk Management'[MeSH] OR</li> <li>• 'service lines' [tw] OR</li> <li>• 'service line' [tw] OR</li> <li>• 'Program Evaluation'[MeSH] OR</li> <li>• 'Regional Health Planning'[MeSH] OR</li> <li>• 'Emergency Treatment'[MeSH] OR</li> <li>• 'Emergency Medical Services'[MeSH] OR</li> <li>• 'Emergency Service, Hospital'[MeSH] OR</li> <li>• 'Emergency Medicine'[MeSH] OR</li> <li>• 'timeliness' [tw] OR</li> <li>• 'Rehabilitation'[MeSH]</li> </ul> | 5,589               | 58,330            |

|  |        |        |
|--|--------|--------|
| <b>Step 3 – Search Quality terms</b>   | 26,885 | 94,947 |
| <ul style="list-style-type: none"> <li>• ‘Quality Assurance, Healthcare’[MeSH] OR</li> <li>• ‘Quality Indicators, Healthcare’[MeSH] OR</li> <li>• ‘Quality-Adjusted Life Years’[MeSH] OR</li> <li>• ‘Quality of Healthcare’[MeSH] OR</li> <li>• ‘Healthcare Quality, Access, and Evaluation’[MeSH] OR</li> <li>• ‘Quality of Life’[MeSH] OR</li> <li>• ‘Cost of Illness’[MeSH] OR</li> <li>• ‘appropriateness’ [tw] OR</li> <li>• ‘Safety Management’[MeSH] OR</li> <li>• ‘patient safety’ [tw] OR</li> <li>• ‘Process Assessment (Healthcare)’[MeSH] OR</li> <li>• ‘performance measures’ OR</li> <li>• ‘Cost-Benefit Analysis’[MeSH] OR</li> <li>• ‘Patient Compliance’[MeSH] OR</li> <li>• ‘Guideline Adherence’[MeSH] OR</li> <li>• ‘Continuity of Patient Care’[MeSH] OR</li> <li>• ‘Efficiency’[MeSH] OR</li> <li>• ‘Efficiency, Organisational’[MeSH] OR</li> <li>• ‘Patient Compliance’[MeSH] OR</li> <li>• ‘Information Systems’[MeSH] OR</li> <li>• ‘Hospital Information Systems’[MeSH] OR</li> <li>• ‘Management Information Systems’[MeSH] OR</li> <li>• ‘Clinical Pharmacy Information Systems’[MeSH] OR</li> <li>• ‘Ambulatory Care Information Systems’[MeSH] OR</li> <li>• ‘Telemedicine’[MeSH] OR</li> <li>• ‘care pathway’ [tw] OR</li> <li>• ‘care protocol’ [tw] OR</li> <li>• ‘practice guideline’ [tw]</li> </ul> |        |        |
| <b>Step 4 – Search Outcome Terms</b>   | 15,595 | 34,489 |
| <ul style="list-style-type: none"> <li>• ‘Health Status’[MeSH] OR</li> <li>• ‘Outcome Assessment (Healthcare)’[MeSH] OR</li> <li>• ‘Mortality’[MeSH] OR</li> <li>• ‘Hospital Mortality’[MeSH] OR</li> <li>• ‘ambulatory care sensitive conditions’ [tw] OR</li> <li>• ‘Morbidity’[MeSH] OR</li> <li>• ‘complications’[Subheading] OR</li> <li>• ‘Sentinel Surveillance’[MeSH] OR</li> <li>• ‘Fatal Outcome’[MeSH] OR</li> <li>• ‘Self Care’[MeSH] OR</li> <li>• ‘Activities of Daily Living’[MeSH] OR</li> <li>• ‘Process Assessment (Healthcare)’[MeSH] OR</li> <li>• ‘outcome’ [tw]</li> </ul>   |        |        |
| <b>Step 5 – intersection of heart failure, health system, quality, and outcome terms</b>   | 91     | 116    |
| Search (((#1)) AND (#2)) AND (#3)) AND (#4)<br>Limited to Research articles (CINAHL)   |        |        |

|  |       |        |
|--|-------|--------|
| <b>Step 6- Search terms related to devices and surgical procedures</b>   | 7,464 | 71,152 |
| <ul style="list-style-type: none"> <li>• (('Pharmaceutical Preparations'[MeSH] OR</li> <li>• 'Drug Evaluation, Preclinical'[MeSH] OR</li> <li>• 'Drug Delivery Systems'[MeSH] OR</li> <li>• 'Drug Evaluation'[MeSH]) OR</li> <li>• ('Equipment and Supplies'[MeSH] OR</li> <li>• 'Heart-Assist Devices'[MeSH]) OR</li> <li>• ('Equipment and Supplies'[MeSH] OR</li> <li>• 'Heart-Assist Devices'[MeSH]) OR</li> <li>• ('Surgery'[MeSH] OR</li> <li>• 'surgery'[Subheading] OR</li> <li>• 'Surgical Procedures, Operative'[MeSH]) OR</li> <li>• 'Coronary Artery Bypass'[MeSH] OR</li> <li>• ('Surgery'[MeSH] OR</li> <li>• 'surgery'[Subheading] OR</li> <li>• 'Surgical Procedures, Operative'[MeSH] OR</li> <li>• 'Angioscopy'[MeSH]))</li> </ul> |       |        |
| <b>Step 7 – Remove articles related to devices and surgical procedures from the intersection of heart failure, health system, quality, and outcome terms</b>   | 85    | 70     |
| Search ((#5)) NOT (#6) Limits: All Adult: 19+ years, English, Publication Date from 2003, Randomized Controlled Trial, Humans  |       |        |